OPERATION MANUAL

MIDMARK®

Diagnostics Group

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A Word of Thanks

Thank you for purchasing the IQmark™ Digital ECG. Midmark Diagnostics Group has used the latest microelectronic and computer software technology to develop a compact, low maintenance and high quality ECG system. Our goal is to enable healthcare professionals to provide quality and efficient patient care. With that in mind, our product is designed with intuitive layouts and features that will enable more physicians to conduct office-based tests, which will result in more timely diagnoses and enhanced patient outcomes.

We believe you will be pleased with the user-friendly operation of our product and with your results. As your partner in healthcare, we look forward to working with you in the coming years as we develop even more sophisticated diagnostic technology for the cardiopulmonary field. Your thoughts, questions, and comments about our product are welcomed.

Midmark Diagnostics Group. PH 800-624-8950 or 310-530-5955

Caution: Federal Law restricts this device to sale to or on the order of a physician.

Physician's Responsibility

The interpretations provided by the Midmark IQmark Digital ECG are for the exclusive use of licensed physicians or personnel under their direct supervision. The suggested interpretation, including numerical and graphical results, should be examined with respect to the patient's overall clinical condition.

It is the responsibility of the physician to ensure proper administration of the test, making a diagnosis, obtaining expert opinions on the results, and instituting the correct treatment.

Notice

The information in this manual is subject to change without notice.

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IQmark is a registered trademark of Midmark.

Windows is a registered trademark of Microsoft Corporation.

Pentium is a registered trademark of Intel Corporation.

Caution

Read the following precautions to ensure proper operation of this instrument.

1. Familiarize yourself thoroughly with the operational procedures of the instrument prior to use.
2. Installation and maintenance of the instrument:
   a) Install and keep the instrument away from splashing water.
   b) Do not install the instrument where humidity, ventilation, direct sunlight or air containing dust, salt, sulfur, etc. might affect it.
   c) Prevent the instrument from slipping and vibration, shock or dropping; be careful when transporting it.
   d) Do not install the instrument in a chemical storage area or where gas is generated.
3. Preparation of the instrument prior to operation:
   a) Verify proper instrument operation.
   b) Check that all cable connections are safe and secured.
   c) When using with other equipment, such as a personal computer, request the assistance of personnel familiar with the equipment.
4. Observe the patient and instrument closely during use. If any abnormality is found, proper action, which may include stopping the operation of the instrument, should be taken immediately for the safety of the patient.
5. Keep the instrument clean to ensure trouble-free operation for the next use.
6. In case of malfunction, call a technician and describe the problem precisely.
7. Inspection the instrument and accessories regularly.
8. Do not make any modifications to the instrument.
9. Environmental operating limits:
   a) Operating: 59 to 95 °F (15 to 35 °C); 30 to 75% humidity (non-condensing); 760mm Hg +/- 20%.
   b) Storage/Shipping: (batteries removed) 4 to 120 °F (-15 to 50 °C); 30 to 95% humidity (non-condensing); 760mm Hg +/- 20%
10. Cautions for the operator:

DANGER: Possible explosion hazard if used in the presence of flammable anesthetics.

WARNING: For continued patient protection, replace only with the same type of patient cable equipped with defibrillation protection devices. Contact Midmark Diagnostics Group for cable replacement.

CAUTION: Refer servicing to qualified service personnel.

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I. General Information

A. Description

Figure 1.0 The IQmark Digital ECG (Serial type - with On/Off switch)

Figure 1.1 The IQmark Digital ECG (USB type - without On/Off switch)

The IQmark Digital ECG is a portable device that converts any Microsoft Windows-based personal computer (PC), be it desktop, laptop, notebook or pen-based, to an electrocardiograph with interpretive capabilities. The device is electronically isolated from the PC and connects to it directly through the USB port or serial port.

Together with the IQmark Diagnostic Workstation (see Operation Manual, part # 3-100-1038), the IQmark Digital ECG makes it easy to record 12-lead ECG, interpret them, archive the reports for future reference and share them with your colleagues via networks or email. As simple to use as a traditional office EKG device, it features fully integrated PC technology and a host of advanced diagnostic features.

Note:

There are two types of IQmark Digital ECG acquisition module, a serial (COM) port type and a USB port type. The serial type ECG module, which has an On/Off switch indicated by ⏻, is designed for use with the Microsoft Windows-based computer and Pocket PC handheld PDA devices. Please refer to the *IQmark Diagnostic PDA Operation Manual* (part # 3-100-1049) for instructions on using it with your Pocket PC device. The USB-type ECG module, which does not require batteries, is designed for using with a Microsoft Windows-based computer only. This manual is written for both types of modules on Windows-based computer systems.

B. Necessary Computer Skills

This manual assumes that you are already capable of using Windows-based applications, that you have some understanding of how a PC works, and that you are familiar with the basic operations of Microsoft Windows. If this is true, you will have no problem using the product. However, in the event that you have any technical questions or problems, please refer to the Troubleshooting Guide in the Appendix of this manual for immediate assistance. Customer Support information is also listed in the Appendix.

C. Configuration

Typical PC Configuration

The block diagram below illustrates the standard configuration of the IQmark Digital ECG system. The primary components are a Windows-based PC, a printer, and the IQmark Digital ECG acquisition module. A portable computer is recommended if mobility is a consideration. Please refer to this diagram when setting up your IQmark Digital ECG system.

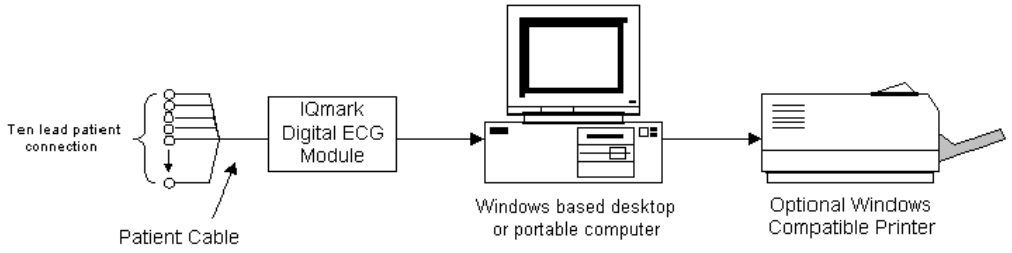
Ten lead patient connection
IQmark Digital ECG Module
Patient Cable
Windows based desktop or portable computer
Optional Windows Compatible Printer

Figure 1.2 Block Diagram for the IQmark Digital ECG system

Typical Thin Client Configuration

If you have a thin client environment, you can install the IQmark Diagnostic Workstation software on the Terminal Server and operate the IQmark Digital ECG through a thin client terminal.

🔔 **NOTE:** Since the thin client terminal does not support the USB type IQmark Digital ECG module, you must have a Serial (RS232) type ECG module and be able to connect to the thin client terminal.

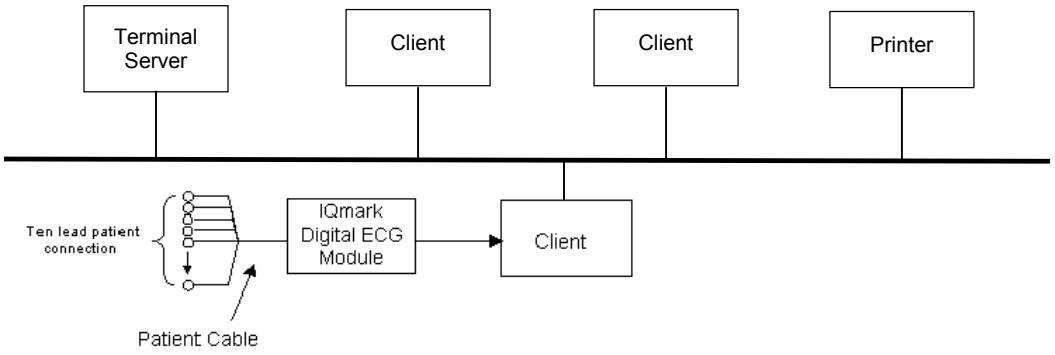

Figure 1.3 Block diagram for the IQmark Digital ECG on a typical thin client environment

Setting up any application on a network environment typically requires special access rights and knowledge of the network. Please have your network administrator install and setup the IQmark Diagnostic Workstation application so it fits your office's needs.

1. Identify the COM port number on the thin client terminal where the ECG module is connected, e.g. "COM1:"
2. Map or redirect the above COM port on the client to the server's COM port, e.g. "COM9:"
3. After the IQmark Diagnostic Workstation is installed on the Terminal Server, select the new COM port, e.g. COM 9, as the ECG COM Port through the IQmark Configuration screen. See sections *II-D Connecting the IQmark Digital ECG module* and *II-E. Configuring the IQmark Digital ECG* on configuring for serial type ECG module.

D. System Specifications

The following are the physical and performance specifications for the IQmark Digital ECG.

Table 1.0 IQmark Digital ECG Specifications

Performance Specifications	
Category	**Specification**
Intended Use	To provide 12-lead resting electrocardiograms, which permit the detection of abnormalities in the transmission of the cardiac impulse through the heart muscle; serves as an important aid in the diagnosis of heart ailments.
Physical Characteristics	• 2.8” (7.1 cm) x 5” (12.7 cm) x .88” (2.3 cm) (W x L x H) • 0.56 lb. (USB type ECG module without batteries) • 0.66 lb. (Serial type ECG module with batteries) • Two 1.5V AA alkaline batteries (Serial type ECG module only) • 25 hours of “ON” time (Serial type ECG module)
Anatomical Sites	• Noninvasive device, 12-lead electrocardiogram
Safety Parameters	• Patient electrically isolated from main current supply. • Patient leakage current not to exceed 10 uA. • Ground leakage current not to exceed 50 uA.
ECG Acquisition	• 12 leads, simultaneous. • Input impedance > 100 MegaOhm • Frequency response 0.05-150 Hz –3 dB • Sensitivity: 5, 10, 20 mm/mV +/- 10% • Dynamic range: +/- 10 mV • ADC resolution: 13 bits at 2.44 uV/bit • Acceptable electrode offset: +/- 300 mV per AAMI and EC-11 specifications. • A/D 500 samples/sec.
Patient Connection	• 10-lead patient cable with RFI filter, defibrillator protection and patient isolation.
Monitor	• Varies by computer system, minimum 800x600 resolution
ECG Analysis & Measurement	• Midmark 12-Lead Resting Electrocardiogram Analysis Program.
Printer	• Windows-supported ink-jet or laser printer.
Paper	• Plain 8.5” x 11” (Letter size) or 210 mm x 297 mm (A4 size)

II. System Installation

🔔 **NOTE:** Please give us a call before you install and set up your IQmark Digital ECG. Computers today are more complex then ever. They come with wide variations of software and hardware options, making your computer almost unique. Midmark wants to make sure that your IQmark Digital ECG is installed and configured as quickly and easily as possible. Please call 1-800-624-8950, and our technical support will make sure your system is up and running in no time.

A. Computer Requirements

The IQmark Digital ECG system employs 32-bit Windows-based medical software. In order to install and successfully use the IQmark Digital ECG system, your computer must meet the following minimum requirements:

- Microsoft Windows-based PC with Windows 98, Windows 2000 or Windows XP.
- Hard disk with a capacity of at least 200 megabytes of free space.
- CD-ROM drive.
- Intel Pentium-class or compatible microprocessor with 500MHz or faster CPU speed.
- VGA display accommodating 800x600, 1024x768, 1280x1024 or higher resolution. Minimum 256 colors (16-bit color recommended).
- 16 MB RAM for Windows 98, or 64 MB RAM for Windows 2000/XP.
- Microsoft compatible mouse.
- Keyboard.
- One high-speed serial port (115 KB per second) or an USB port.

B. Hardware Installation

1. Remove the IQmark Digital ECG from its packaging, and verify that you have the following items:

    - IQmark installation CD
    - IQmark Diagnostic Workstation operation manual
    - IQmark Digital ECG operation manual
    - IQmark Digital ECG acquisition module
    - Patient cable (10-lead)
    - 10 universal clips
    - Package of electrodes

- Four (4) AA alkaline batteries (for serial type ECG module)
- USB to serial port adapter (for serial type ECG module)

2. A. For the serial type ECG module, slide out and remove the battery door underneath the module and install 2 AA batteries. Be sure to follow the battery positions indicated. Replace the battery compartment door.

   B. For the USB type ECG module, no batteries are required.

3. A. For the serial type ECG module, attach the female end of the 9-pin communication cable to any available serial port on the PC. If you are using a USB port with the serial type ECG module, install the USB to serial port adapter before you connect the ECG module to the adapter. Secure the connections with the thumbscrews. Do not over tighten.

   NOTE:
   Almost all USB to serial port adapters come with specific software drivers that must be installed prior to use. Before connecting the IQmark ECG module to any adapter, ensure that all software drivers have been installed according to the manufacturer's instructions.

   B. For USB type ECG module, DO NOT connect the module to the computer until the IQmark Diagnostics Workstation software is installed.

4. Attach the patient cable to the 15-pin connector on the ECG acquisition module (refer to figure 2.0).

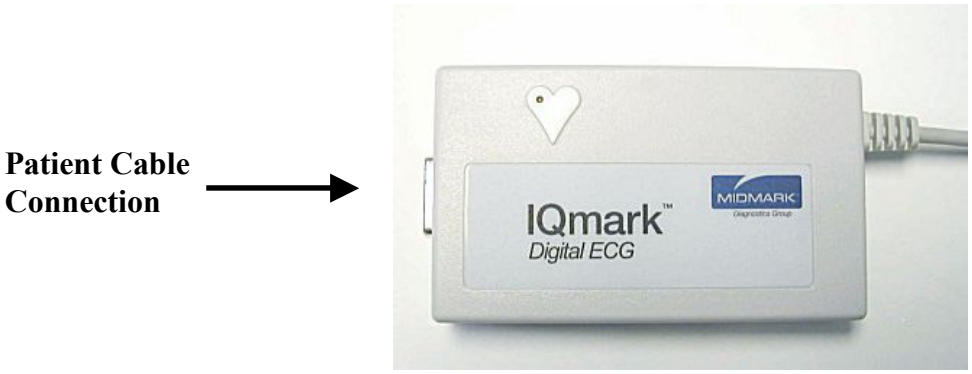

Figure 2.0 IQmark Digital ECG Acquisition Module.

C. Software Installation

The medical diagnostic application, IQmark Digital ECG**,** uses the IQmark Diagnostic Workstation to manage patient records. When you install or upgrade the IQmark Digital ECG, the IQmark Diagnostic Workstation is automatically installed or upgraded

accordingly (see the *IQmark Diagnostic Workstation Operation Manual* #3-100-1038, for further information).

You can also access other IQmark products, such as the IQmark Digital Holter, IQmark Digital Spirometer, Digital Stress, Vital Signs Interface and Weight/Scale Interface from the IQmark Diagnostic Workstation. Call Midmark Sales Department for the latest information on available IQmark products.

NOTES:

- *If you already have IQmark Diagnostic Workstation installed on your computer and you are now either upgrading or adding a new IQmark product, please* ***skip*** *this section and refer to the* IQmark Diagnostic Workstation Operation Manual *for detailed installation information.*
- *Close all Windows programs before installing this software. Do not interrupt the installation program while it is running. The installation should take less than five minutes.*

Before installing the IQmark Digital ECG on your computer, it is important that you understand and carry out the following tasks.

Windows Taskbar

The IQmark Digital ECG is designed to run as a full-screen program. For best results, the Windows Taskbar should not be displayed in order to provide maximum display area. Place the mouse pointer on the blank portion of the Taskbar on the bottom of the screen, then right-click and select Properties. Ensure Always on top is NOT checked.

Screen Saver

If a screen saver or any energy saving feature is enabled on the computer, make sure that it does not activate and interfere with data acquisition during patient care. Refer to your computer or software manual for these settings.

Installation Steps

1. Insert the Installation CD into the CD-ROM or DVD-ROM drive. The installation starts automatically. If the installation does not start automatically, double-click My Computer on the desktop and double-click the CD-ROM icon to start.
2. Follow the instructions on the screen. For detailed installation, setup and detailed operation instructions, please refer to the *IQmark Diagnostic Workstation Operation Manual*.

D. Connecting the IQmark Digital ECG module

Serial type ECG module

If you have a serial type ECG module, attach the female end of the 9-pin communication cable to any available serial port on the PC. If you are using a USB port with the serial type ECG module, install the USB to serial port adapter before you connect the ECG module to the Adapter. Secure the connections with the thumbscrews. Do not over-tighten.

NOTE: Almost all USB to serial port adapters come with specific software drivers that must be installed prior to use. Before connecting the IQmark ECG module to any adapter, ensure that all software drivers have been installed according to the manufacturer's instructions.

USB type ECG module

If you received a USB type ECG module, you can connect it to any available USB port on the computer after the IQmark Diagnostic Workstation is installed. As with other USB devices, Windows will attempt to identify the ECG module the first time it connects to it. This may take a few seconds.

E. Configuring the IQmark Digital ECG

Through the IQmark Configuration program, you can customize the IQmark Diagnostic Workstation and the IQmark Digital ECG for your operation. If you are using the database on your local and network computers, the configuration program also enables you to set your default database.

The configuration program can be accessed from the Windows Taskbar through the following sequence:

Start → Programs → Midmark Diagnostics → IQmark Configuration

Or double-click the following IQmark Configuration icon on the Desktop:

The following dialog box appears.

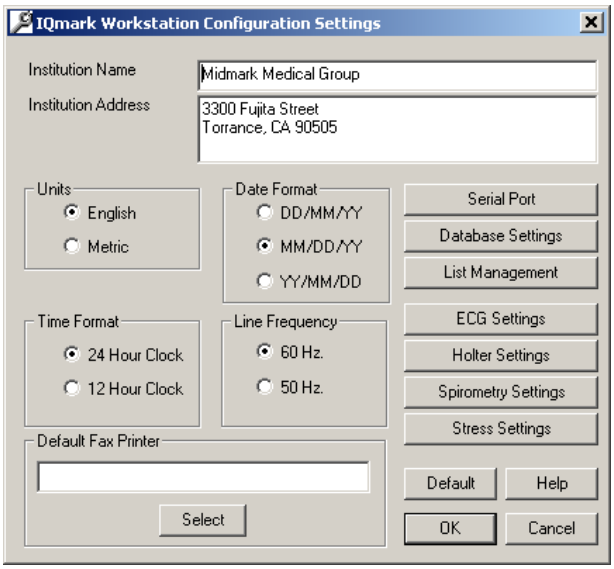

Figure 2.1 Configuration Settings Dialog Box

Complete the Institution Name and Institution Address boxes with information about your own medical practice. The IQmark Digital ECG will display your institution name on each of the procedure screens and on printed reports. Enter a name that describes your practice or operation to enable other medical personnel to identify your reports.

You may choose between International (metric) and American (English) units of measurement, and between the AC power source frequencies of 50 Hz or 60 Hz. The IQmark Digital ECG uses the latter information to filter out background noise introduced by the power source through its AC filter. In the United States, this frequency is 60 Hz. If you are using this product outside of the United States, please consult with the local power utility company to determine the appropriate frequency.

Configuring for Serial Type ECG Module

If you have a serial type ECG module, you can select the serial port for the ECG module in the configuration screen (Fig. 2.1). Click the Serial Port button to open the following dialog box.

🔔 **NOTE:** The default serial communications port is COM 1.

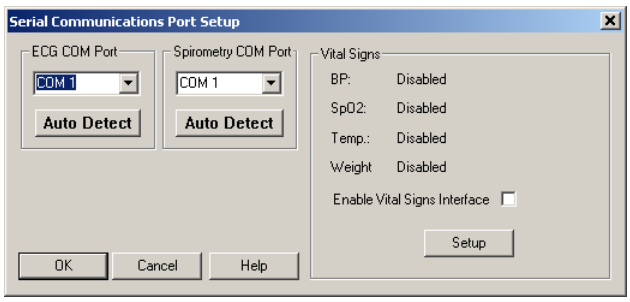

Figure 2.2 Serial Communications Port Setup For Serial Type ECG Module

Use the Auto Detect button to find the port that the ECG module is connected to (see Section II-E). To use Auto Detect, you must have the ECG module connected to an available serial port on the computer. Confirm that a fresh set of batteries is installed in the ECG Module and click the left Auto Detect button. The result of the auto detection appears on the screen. Some ECG modules may need to be turned on manually for Auto Detect to work. Simply press the ⏻ switch to turn on the module.

Configuring for USB Type ECG Module

If you received a USB type ECG module and it is already connected to the computer, the ECG COM Port setting will be disabled once it is detected as shown below.

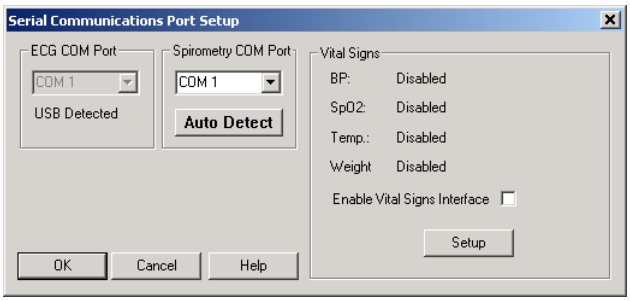

Figure 2.3 Serial Communications Port Setup For USB Type ECG Module

Database Settings

The IQmark Diagnostic Workstation uses the local database by default. If you have setup the database on a network, you will have the option to select between the local or network to be the default database. Click the Database Settings in the configuration screen (Fig. 2.1) for this option.

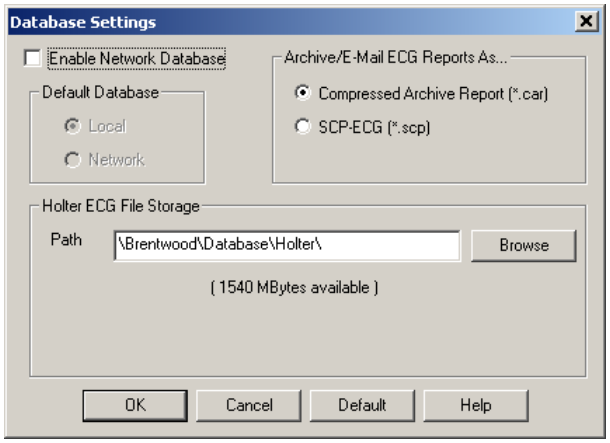

Figure 2.4 Database Settings

To select Network database as your default, first check the Enable Network Database box, then click Network. Refer to the IQmark Diagnostic Workstation operation manual for more details on setting up a network database.

The IQmark Diagnostic Workstation allows you to archive the ECG reports from the database as individual files. It also allows you to send the ECG reports using your default E-mail program. The default format for this report is Compressed Archive Report (*.car). The SCP-ECG (*.scp) format is more popular in the European countries.

If you have purchased an IQmark Holter product, you also have the choice to select a different location to store your Holter ECG files.

List Management

The List Management button on the configuration screen (Fig. 2.1) enables you to add or customize medications, history statements, race categories, ECG/Holter indications and ECG diagnostic statements. You can also enter the names of the doctors and technicians using the Workstation. Once these items are entered, you can later select them from the appropriate lists in the test without having to retype them.

Click List Management in the configuration screen (Fig. 2.1) and choose to configure the lists for your local database or network database. If the network database is not setup, the Network Database selection will be disabled as shown below.

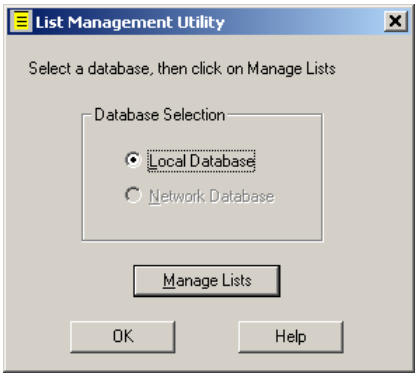

Figure 2.5 List Management Utility

Click Manage Lists and the following dialog box appears. You can add, edit, or delete any item in the Medications, History Statements, ECG/Holter Statements and Race Categories lists.

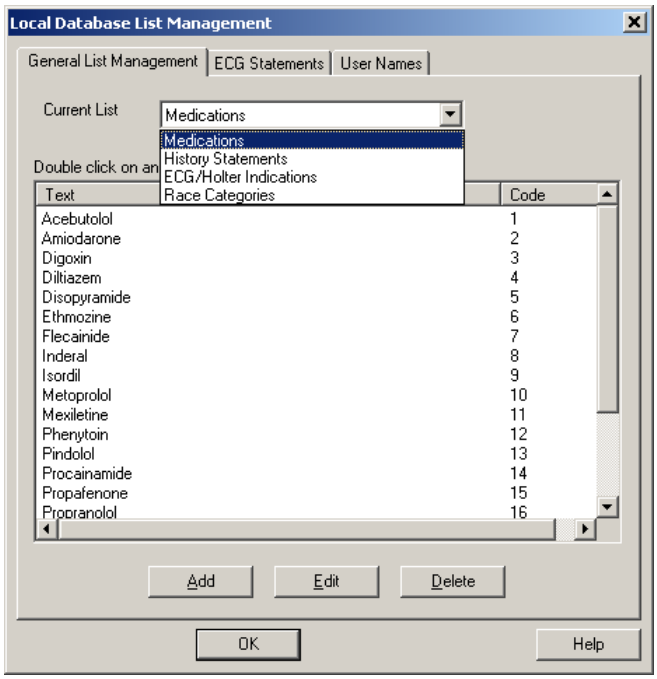

Figure 2.6 List Management - General List Management

Select the ECG Statements tab to view the default ECG statements. These statements will be available to you when editing the ECG interpretations online.

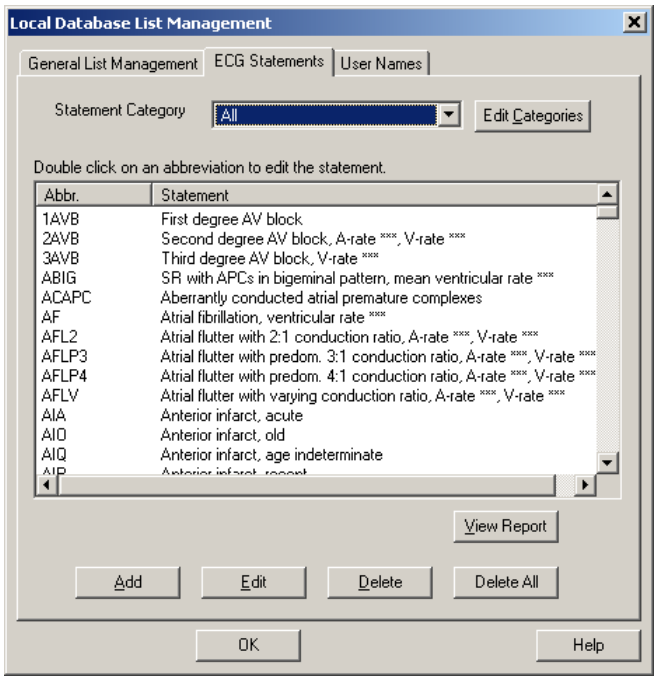
Local Database List Management
General List Management
ECG Statements
User Names
Statement Category
All
Edit Categories
Double click on an abbreviation to edit the statement.
Abbr.
Statement
1AVB First degree AV block
2AVB Second degree AV block, A-rate ***, V-rate ***
3AVB Third degree AV block, V-rate ***
ABIG SR with APCs in bigeminal pattern, mean ventricular rate ***
ACAPC Aberrantly conducted atrial premature complexes
AF Atrial fibrillation, ventricular rate ***
AFL2 Atrial flutter with 2:1 conduction ratio, A-rate ***, V-rate ***
AFLP3 Atrial flutter with predom. 3:1 conduction ratio, A-rate ***, V-rate ***
AFLP4 Atrial flutter with predom. 4:1 conduction ratio, A-rate ***, V-rate ***
AFLV Atrial flutter with varying conduction ratio, A-rate ***, V-rate ***
AIA Anterior infarct, acute
AIO Anterior infarct, old
AIQ Anterior infarct, age indeterminate
View Report
Add
Edit
Delete
Delete All
OK
Help

Figure 2.7 List Management – IQmark Default ECG Statements

The Delete All button will delete all ECG statements so that you can enter your own diagnostic statements from scratch or choose from the two lists available through the Load Default Statements button.

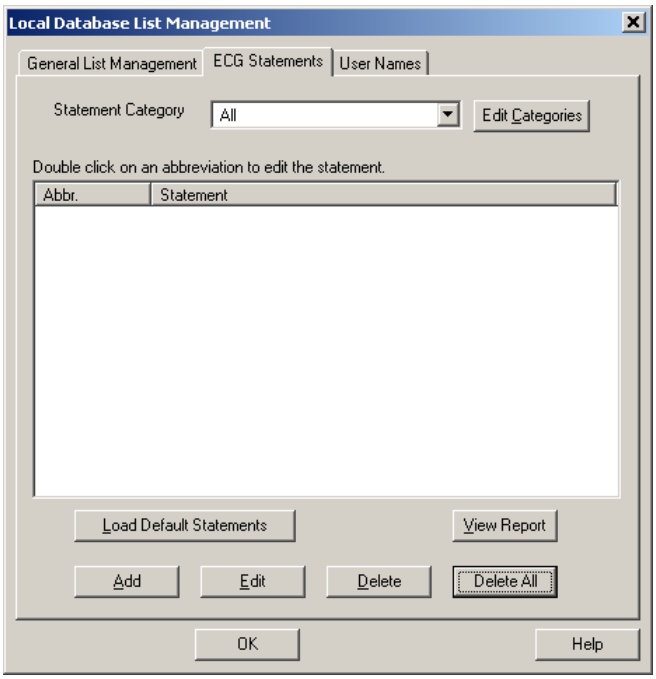

Figure 2.8 List Management – Load Default Statements

The two ECG statement list options are IQmark Default List or AAMI SCP-ECG.

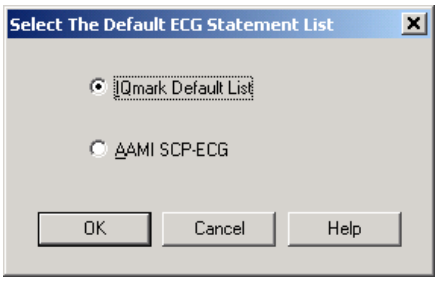

Figure 2.9 List Management – Select Default ECG Statements

The IQmark Default List is the default list installed with the IQmark Diagnostic Workstation.

To enter the names of doctors and technicians who use the Workstation, select the User Names tab. Click the Add button. You can type in a user's name and define the user as a physician, technician, or both.

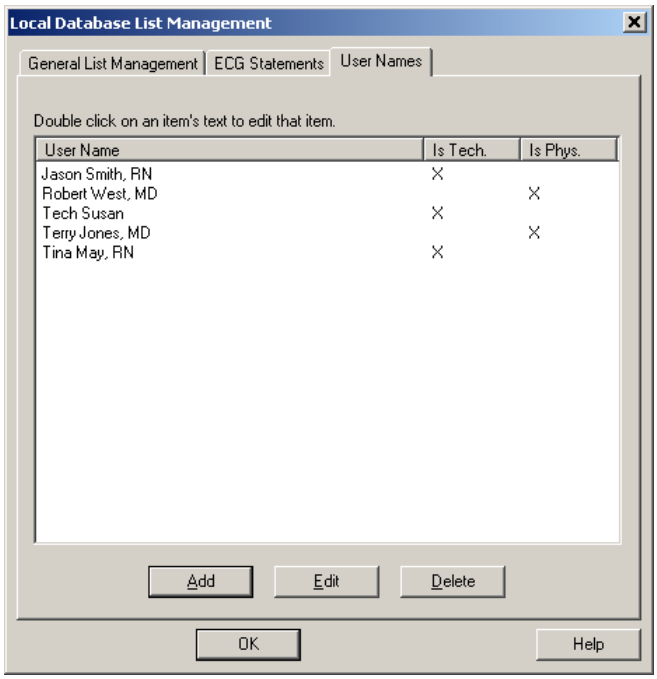

Figure 2.10 List Management – User Names

Click OK to close the List Management Utility.

ECG Settings

You can set the default settings use for ECG tests by clicking the ECG Settings button in the configuration screen (Fig. 2.1). The following dialog box appears.

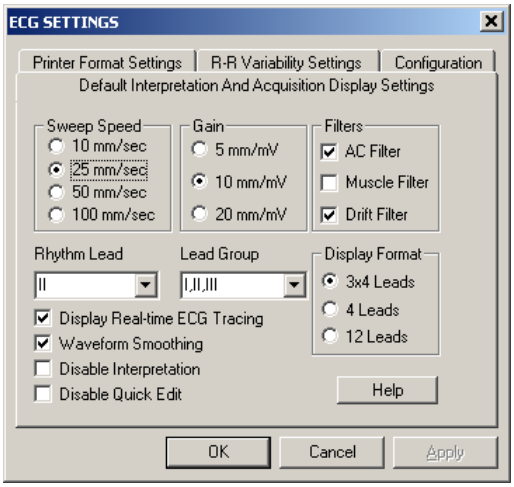

Figure 2.11 ECG Settings – Default Interpretation And Acquisition Display Settings

The following table explains the setting options available.

Default Interpretation And Acquisition Display Settings		
Item	**Settings**	**Comments**
Sweep Speed	• 10 mm/sec • 25 mm/sec • 50 mm/sec • 100 mm/sec	Default setting is 25 mm/sec. Sweep Speed setting only applies to real time ECG display. The ECG report only prints at 25mm/sec scale, except if a 2-Page Format is selected. See Printer Format Settings.
Gain	• 5 mm/mv • 10 mm/mv • 20 mm/mv	½ gain Standard gain – default setting. 2X gain
Filters	• Muscle: On/Off • AC: On/Off • Drift: On/Off	Default settings are MYO: Off, AC: On, Drift: On. See Note on Filters following this table.
Rhythm Lead	Select any lead.	Default setting is lead II. This setting applies to both the 3x4 and 4-lead display formats, and to the RR Variability analysis rhythm lead.
Lead Group	• I, II, III • aVR, aVL, aVF • V1, V2, V3 • V4, V5, V6	Default setting is I, II, III. This setting applies to the 4-lead display format.
Display Format	• 3x4 leads plus rhythm • 4 leads • 12 leads	Default setting is 3x4 plus rhythm lead.
Display Real-time ECG Tracings	• On/Off	Default setting is On (checked). If this setting is Off (cleared), the live ECG screen will not display real time tracings while acquiring ECG data. Set it to Off (cleared) only if your computer has problem with displaying real-time ECG.
Waveform Smoothing	• On/Off	Default setting is On. Controls how the ECG waveforms are drawn in the real-time display screen. Selecting On produces smoother waveforms. In contrast, selecting Off may produce waveforms that appear jagged. **Note**: If you are using a slow PC or having delayed ECG tracing, use the Off setting.
Disable Interpretation	• On/Off	Default is off (cleared). If On (checked), the ECG will not produce any diagnostic statements and the interpretation portion of the report, ECG Review and the Edit Screen will be blank.

Default Interpretation And Acquisition Display Settings		
Item	**Settings**	**Comments**
Disable Quick Edit	• On/Off	Default is off (cleared) If On (checked), the software defaults to free text entry method for adding any diagnostic statements, instead of the Quick Edit feature of the Add a Statement dialog box (see "Editing Diagnostic Statements").

Table 2.0 Default Interpretation and Acquisition Display Settings

NOTE on Filters: For all pacemaker patients, it is **strongly recommended** that ECG be performed with all filters turned off, particularly the MYO filter. Any artifacts in the ECG should be corrected at the source, i.e., making sure the electrode sites are clean of lotion or body hair, the electrodes are fresh and sticky and are adhering properly on the skin. Refer to "ECG signal quality problems…" in the Troubleshooting Guide for more details.

Click Printer Format Settings tab of the ECG Settings (Fig. 2.11) to select the default ECG report format, as shown below.

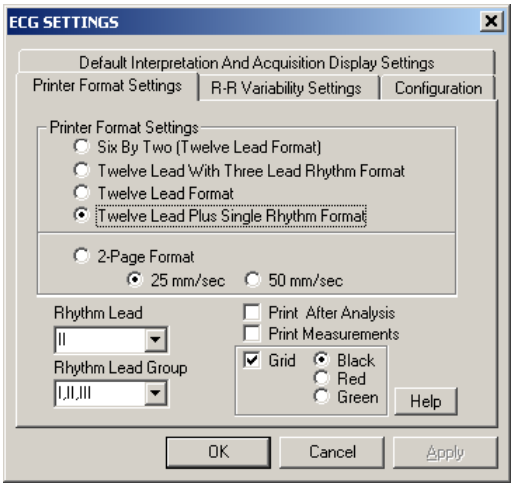

Figure 2.12 ECG Settings – Printer Format Settings

The following table explains the ECG report printing options available.

Printer Format Settings		
Item	**Settings**	**Comments**
Printer Format Settings	• 6 x 2 format • 12-lead with 3-lead rhythm format (3x4+3) • 12-lead format (12x1) • 12-lead plus single rhythm format (3x4+1) • 2-Page Format	Default setting is 12 lead plus single rhythm format. 2-Page Format prints leads I, II, III, aVR, aVL, and aVF on the first page and V1-V6 on the second page. You can select the print scale of 25 mm/sec or 50 mm/sec when printing in 2-page format. Other formats will always print at 25mm/sec scale.
Rhythm Lead	Select any lead.	Default setting is II. Applies to 12-lead with single rhythm format.
Rhythm Lead Group	• I, II, III • aVR, aVL, aVF • V1, V2, V3 • V4, V5, V6	Default setting is I, II, III. Applies to 12-lead with 3-lead rhythm format above.
Print After Analysis	On/Off	Default setting is Off (cleared). When On (checked), resting ECG report is printed automatically following analysis. **Recommendation**: To speed up printing, set to Off and print report manually after the ECG is acquired.
Print Measurements	On/Off	Default setting is Off (cleared). When On (checked), the detailed measurement matrix report is printed automatically with the ECG report.
Grid	On/Off Black, Red or Green	Default setting is On (checked). When on, grid is printed in the selected color if a color printer is used.

Table 2.1 Printer Format Settings

Click R-R Variability Settings tab of the ECG Settings (Fig. 2.11 or 2.12) to preset the default test duration and report format, as shown below.

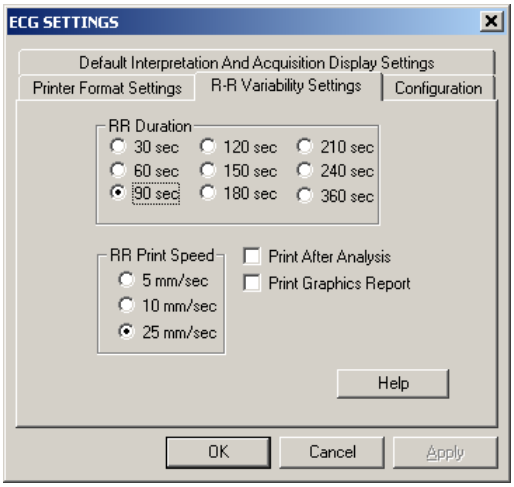

Figure 2.13 ECG Settings – R-R Variability Settings

The following table explains the settings for acquiring and printing a R-R Variability report.

R-R Variability Settings		
Item	**Settings**	**Comments**
RR Duration	• 30 sec • 60 sec • 90 sec • 120 sec • 150 sec • 180 sec • 210 sec • 240 sec • 360 sec	Default setting is 90 sec. This setting defaults the length of the rhythm strip acquired through Start R-R test. The rhythm strip is defined in the ECG Settings (Fig. 2.11).
RR Print Speed	• 5 mm/sec • 10 mm/sec • 25 mm/sec	Default setting is 25 mm/sec. This setting defines the print scale of the ECG tracings for R-R test.
Print After Analysis	On/Off	Default setting is Off (cleared). When set to On (checked), the R-R test report is printed automatically following successful completion of R-R test analysis. **Recommendation**: To speed up printing, set to No and print report manually after the test is completed.

R-R Variability Settings		
Item	**Settings**	**Comments**
Print Graphics Report	On/Off	Default setting is Off (cleared). When set to On (checked), the graphic report, which includes the R-R Trend and R-R Histogram, is printed automatically with the R-R rhythm strip report.

Table 2.2 R-R Variability Settings

Click Configuration tab of the ECG Settings (Fig. 2.11, 2.12 or 2.13) to access the Configuration settings.

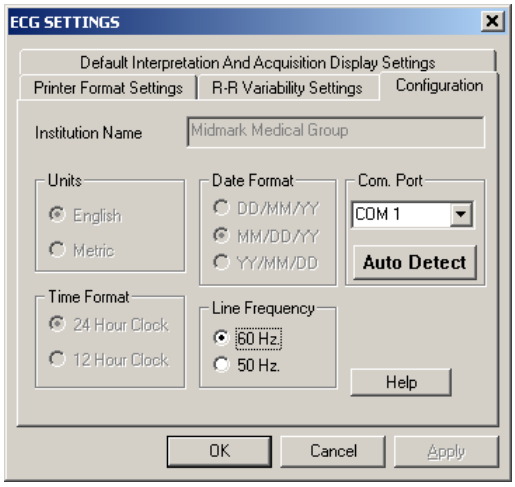

Figure 2.14 ECG Settings – Configuration

Most of the settings on this screen are controlled by the IQmark Workstation Configuration Settings (Fig. 2.1) and therefore cannot be changed, except the line frequency and COM port auto detection for ECG module. You can make changes to these settings on either screen.

Click OK on the ECG Settings screen (Fig. 2.11) if you want to save any changes you made. It will return you to the Configuration Settings dialog box (Fig. 2.1). Please refer to the appropriate operation manuals for details on Holter, Spirometry and Stress Settings.

Once you are satisfied that the configuration settings are set appropriately, click OK on the Configuration Settings dialog box (Fig. 2.1) to store the settings. These settings will become effective the next time the IQmark Diagnostic Workstation is started. If you decide not to make changes to the configuration, simply press Cancel. You can also click Default to restore the IQmark Diagnostic Workstation configuration settings (except Institution Name, Address and List Management) to their default values.

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III. Operation

WARNING

The IQmark Digital ECG module has been designed and tested to meet IEC 60601-2-25 and AAMI EC11 defibrillation protection standards. In the event of defibrillation, follow the instructions on your defibrillator and adhere to all warnings and cautions.

A. Introductory Notes

This manual describes how to use the various IQmark Digital ECG features in the operational sequence most new operators will follow. However, this does not mean that you are restricted to following this particular sequence. Many of the features are interconnected and can be accessed from more that one screen. The menu bar, buttons or tabs on each screen lead you to a different screen or feature. To enter any of these screens, simply click once on the appropriate selection.

Of course, there are certain sequences that must always be followed, such as entering a patient's medical data prior to acquiring an ECG. Overall, we believe that you will find this program to be both user-friendly and flexible.

For your convenience, we have included a condensed guide to the operation of the IQmark Digital ECG with new patients in the Appendix under "Operations at a Glance" (Section IV-A). It can be used when you are familiar with the use and operation of the program.

B. Preparation

Prior to initiating the ECG acquisition program for resting ECG or R-R Variability analysis, you must ensure that the patient is prepared for the procedure. It is essential that you comply with the following instructions on patient preparation as closely as possible. Otherwise, the integrity of ECG data can be compromised.

Instructions for Performing ECG Acquisition

Note: Please refer to the Quick Reference User's Guide – Performing a 12-lead Resting ECG Test for more detailed instructions.

Patient Position:

The patient should be placed comfortably in a supine position. Any variation should be noted on the ECG report.

Electrodes:

When using disposable electrodes, check to ensure the electrode is fresh and sticky. Always make sure your fingers are clean and free of lotion when handling electrodes.

Skin Prep:

Patients with excessive chest hair should be shaved at the electrode site. Abrade these areas with fine sandpaper or an abrasive pad, and then clean with an alcohol-saturated gauze. Allow the skin to air dry.

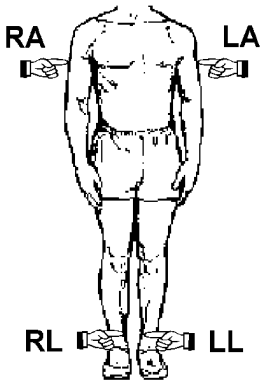
Limb Lead Placement:

RA (White) – Right Arm electrode is placed on a distal portion of the right lateral side of the upper arm below the shoulder.

LA (Black) – Left Arm electrode is placed on a distal portion of the left lateral side of the upper arm below the shoulder.

RL (Green) – Right Leg electrode is placed on a distal portion of the lower leg, above the ankle.

LL (Red) – Left Leg electrode is placed on a distal portion of the lower leg, above the ankle.



Precordial Lead Placement:

V1 (Red) – 4th intercostal place at the right margin of the sternum.

V2 (Yellow) – 4th intercostal place at the left margin of the sternum.

V3 (Green) – Midway between V2 and V4 (on top of the 5th rib).

V4 (Blue) – 5th intercostal place at the left mid-clavicular line.

V5 (Orange) – At the horizontal level of V4, at the left anterior line.

V6 (Purple) – At the horizontal level of V4, at the mid-axillary line.

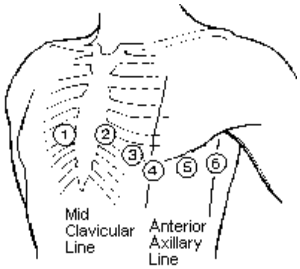


Figure 3.0 ECG Hookup Diagrams

NOTE: Lead placement does affect the ECG waveform. When the limb leads are placed on the torso, waveform changes might be seen in the QRS amplitude, axis shift occurs, Q waves can be seen, and T waves might appear flipped or flattened. These changes are clinically significant in that they are associated with cardiac ischemia. If a non-standard lead placement is used, note the variation in the ECG comment field.

C. Starting the Program

You start the ECG test through the **IQmark Workstation**, located on your Windows Desktop as a shortcut icon. Double clicking on this icon starts the Workstation program.

Or start from the Windows Taskbar through the following sequence:

Start → Programs → Midmark Diagnostics → IQmark Diagnostic Workstation

NOTE: For a detailed description of other diagnostic functions available through the IQmark Workstation, please see the *IQmark Diagnostic Workstation Operation Manual* (part# 3-100-1038).

D. Opening Screen

When you start the IQmark Diagnostic Workstation, an opening screen appears.

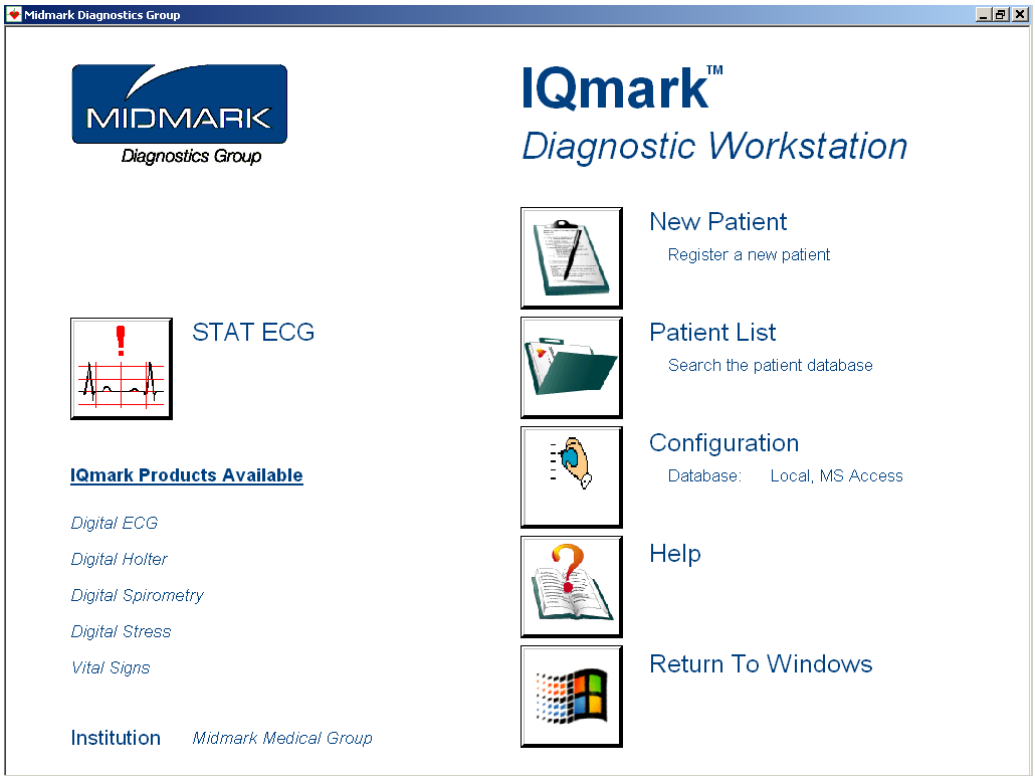


Figure 3.1 Opening Screen

STAT ECG

In the event that a stat ECG is required, hook up the patient to the IQmark Digital ECG and click on the STAT ECG button to immediately access the live ECG test screen without having to enter the patient information. You can either print a live ECG report without saving the patient test or click Analyze to have the computer analyze and save the report. You are prompted to enter the patient information when you exit the report review screen.

NOTE: The green LED on the ECG module will light when the module is on.
If you have a serial type ECG module with an On/Off switch indicated by the ⏻ symbol, and if the LED is not lit at this time, you may need to turn it on manually by pressing ⏻.
If you have a USB type ECG module, the Workstation software will turn on the module automatically as needed.

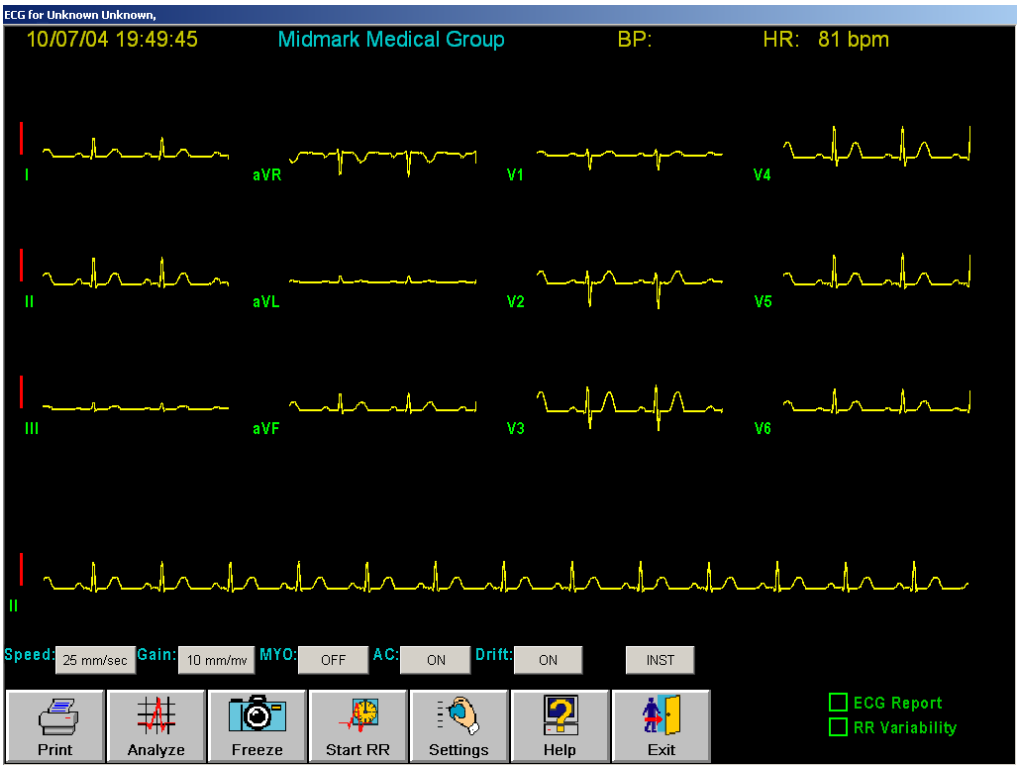
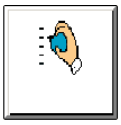


Figure 3.2 Stat ECG screen

For normal operation, there are five choices on the opening screen (Fig 3.1):

Allows the operator to register and proceed with ECG acquisition for a new patient.

Allows the operator to view a list of patients already tested via the IQmark Workstation or entered into the database. Select a patient from the list to access their records from previous tests. Please refer to the *IQmark Workstation Operation Manual* (#3-100-1038) for detailed descriptions.



Allows the operator to view and customize the Workstation Configuration Settings. See Fig. 2.1 Configuring Settings Dialog Box

Provides online assistance with the use, operation, and troubleshooting of the IQmark Diagnostic Workstation and other products. The About Workstation displays the versions of various IQmark software products installed.

Exits the program and returns to the Windows Desktop.

E. Testing A New Patient

To register new patients, click the New Patient button on the opening screen (Fig. 3.1). The Patient Data Entry screen appears. The Patient Data screen enables you to enter data that is pertinent to your patient.

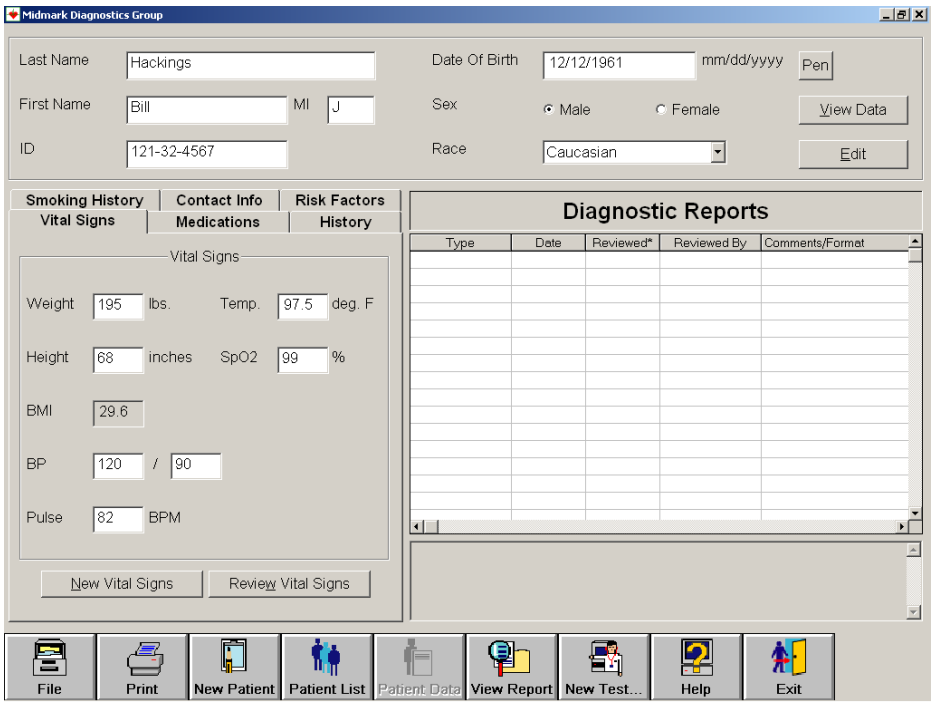


Figure 3.3 Patient Data Screen

NOTE: You **must** enter a name or ID for the patient to start a new test.

Click in any text box or press the tab key to enter information. Although all this information is not essential for the acquisition of an ECG, it is important to complete each of these fields as accurately as possible, particularly Date of Birth, Sex, and Medications, which are used by the Midmark 12-Lead Resting ECG Analysis Program to produce diagnostic statements. The blood pressure values entered will be displayed and printed on the ECG report.

The Midmark analysis program is capable of interpreting ECG from infant to adult age by using the appropriate age dependent criteria. It automatically calculates the age of the patient based on the date of birth entered on the Patient Data screen, and the current date of your computer. Please make sure that the date and time on your computer is current.

Please refer to the *IQmark Diagnostic Workstation Operation Manual* (#3-100-1038) for additional information on the Patient Data screen.

Live ECG

Once the patient is prepared, calm, and comfortable, initiate ECG data acquisition by clicking the New Test button on the menu bar at the bottom of the Patient Data screen (Fig. 3.3). The New Test dialog box appears, on which you can select the test type to run. Click the ECG icon in the left-hand portion of the dialog box.

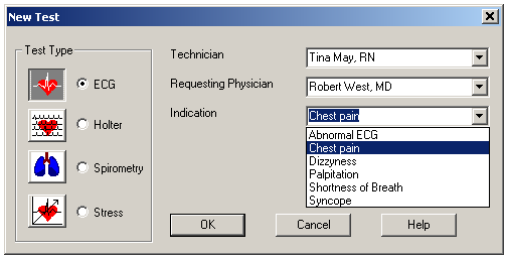


Figure 3.4 New Test Dialog Box

Enter the names of the technician conducting test and the requesting physician. Enter the diagnostic reason for performing the ECG in the Indication field. This information is optional.

If you have configured the list management for your practice, you can select these entries from the lists.

Click OK button to open the live ECG screen.

NOTE: The green LED on the ECG module will light when the module is on. If you have a serial type ECG module with an On/Off switch indicated by the ⏻ symbol, and if the LED is not lit at this time, you may need to turn it on manually by pressing ⏻.

If you have a USB type ECG module, the Workstation software will turn on the module automatically as needed.

NOTE: The laptop computer's AC Adapter may introduce electrical interference. For best ECG result, do not use the AC Adapter while running a live ECG.

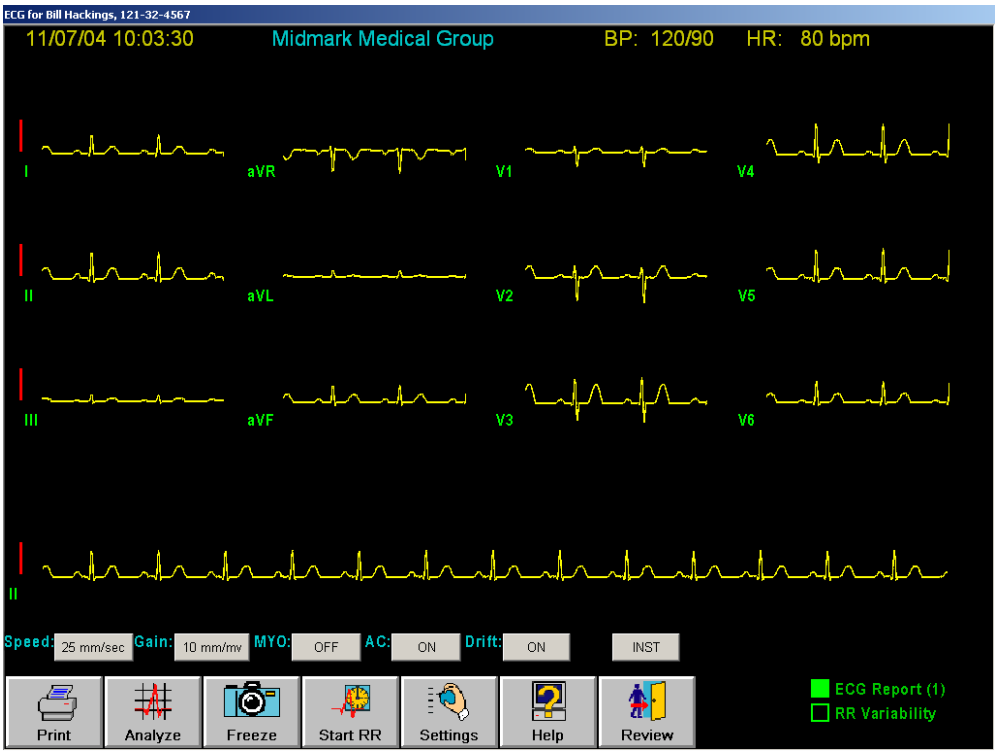


Figure 3.5 Live ECG Screen

The live ECG screen displays the results of the 12-channel ECG in the three-by-four (3x4) leads display format. This format can be changed by using the Settings function, which is explained later. Your facility's name, the date, time and the patient's heart rate appear at the top of the screen. The ECG tracings are in the center of the screen moving from left to right.

Below the moving tracings are the sweep speed, gain, and filter settings. You can click the appropriate button to modify its setting. Changes made here to these settings are temporary and only apply for as long as you are in this test. You can change and set them as the default settings for all new ECG tests through the Settings button.

Clicking on the INST button resets the ECG module and stabilizes the ECG baselines. If there is no INST button on the screen, manually turning the ECG module power off for one second and then turning it on would accomplish the same effect.

In the lower right corner of the screen are the status indicators for ECG Report and RR Variability. An empty status indicator means that you have not acquired the specific report since entering the screen. Once a report is created, the indicator next to the test

type appears solid. This indicator is not affected by tests that were previously stored or reviewed in the database.

The menu bar at the bottom of this screen provides different options you can take. These available options change according to the settings and the process you have made.

Print:	Prints the last 10 seconds of ECG data being collected. This report contains no measurements or diagnostic statements. If data is not actively being collected (see Freeze below), this function prints out the last 10 seconds of data in memory. **NOTE:** Do not click on this button more than once before the report is printed, as each click produces a separate printout. The Exit button (see below) is disabled until the report is printed. To speed up printing, Freeze the display before clicking Print.
Analyze:	Performs resting ECG analysis on the last 10 seconds of data, and stores this analysis as an ECG Report. This report can be printed out from the Report Review screen or automatically by selecting Print After Analysis in the Printer Format Settings (see Settings function below).
Freeze:	Freezes the display and copies the last 10 seconds of ECG data into a memory buffer. If there are less than 10 seconds of ECG data collected, the freeze function is delayed until the 10-second buffer is filled. Click this button a second time to unfreeze the display and clear the memory buffer. When the display is frozen, you can also click the Print or Analyze button.
Display:	This option is only available if the Display Real-time ECG Tracing is disabled in the Settings (Table 2.0). Click on this button to display the ECG tracing acquired in the last 10 seconds. Tracings are displayed in static form and are not stored. Click on the Analyze button to analyze and save the ECG displayed.
Acquire:	This option is only available if the Display Real-time ECG Tracing is disabled in the Settings (Table 2.0). Click on this button to start new acquisition of ECG data. A message "Acquiring ECG…" will display on screen.
Start RR:	Instructs the program to collect ECG data for R-R Variability analysis. A preset duration between 30 and 360 seconds of ECG data may be collected in 30-second increments (see Settings function below). Stop data collection by clicking this button a second time. No RR Variability analysis is performed if less than 30 seconds of data have been collected. Otherwise, the program will automatically analyze the data and store the report. Print RR Variability reports by clicking the Exit button and selecting Print, or select Print After Analysis in the RR Variability Settings to print reports automatically (see Settings function below).

Settings:	The Settings button opens a four-tab dialog box for changing the Default Interpretation And Acquisition Display Settings, Printer Format Settings, R-R Variability Settings and Configuration, which are similar to those described in section II-E, "Configuring the IQmark Digital ECG" (see Tables 2.0, 2.1 and 2.2).
Help:	Displays the online Help screen.
Exit:	Exit indicates an ECG or R-R Variability Report has not been collected. Click this button to return to the previous screen (the Patient Data screen) and terminates ECG acquisition.
Review:	Review indicates at least an ECG or R-R Variability test has been performed. Click to display the most recent report in the Review Reports screen.

The IQmark Digital ECG collects and stores a test report when you click on Analyze or Start RR from the Live ECG screen (Fig. 3.5). Selecting Analyze instructs the program to acquire, analyze and store a resting ECG Report. Selecting Start RR instructs the program to begin acquisition for an R-R Variability Report. When a minimum of 30 seconds of ECG data has been acquired, the program proceeds to analyze the data and will store an R-R Variability report in the Workstation database. There is no limit to the number of reports you can collect for a given patient using the Analyze and Start RR functions.

Both the resting ECG and RR Variability reports are automatically stored in the designated database for future reference, whether locally on your computer hard drive or remotely in a central database. The IQmark Diagnostic Workstation provides many record management features that make it easy for you to retrieve and review this information later.

F. Reviewing Patient Reports

After a report has been collected through Analyze or Start RR, clicking the Review button on the Live ECG screen (Fig. 3.5) will automatically bring you to the Report Review screen. Data from the latest report collected will be displayed, with the format reflecting the method of collection, i.e. either by Analyze or Start RR function.

ECG Report Review

Reports collected using the Analyze function are displayed on the Report Review screen with ECG data traces from each of the patient leads. You can click on any part of the

ECG tracings to zoom in to view in 2X magnification. While in this mode, you can move, or pan, the ECG tracings to view the other leads by holding down the Shift key and dragging with the mouse. Click again on the ECG tracings to return to the normal view.

If the ECG amplitude is too tall or too short, you can click the Gain 1X button to increase the amplitude gain to 2X (20mm/mv) or decrease to 1/2X (5mm/mv).

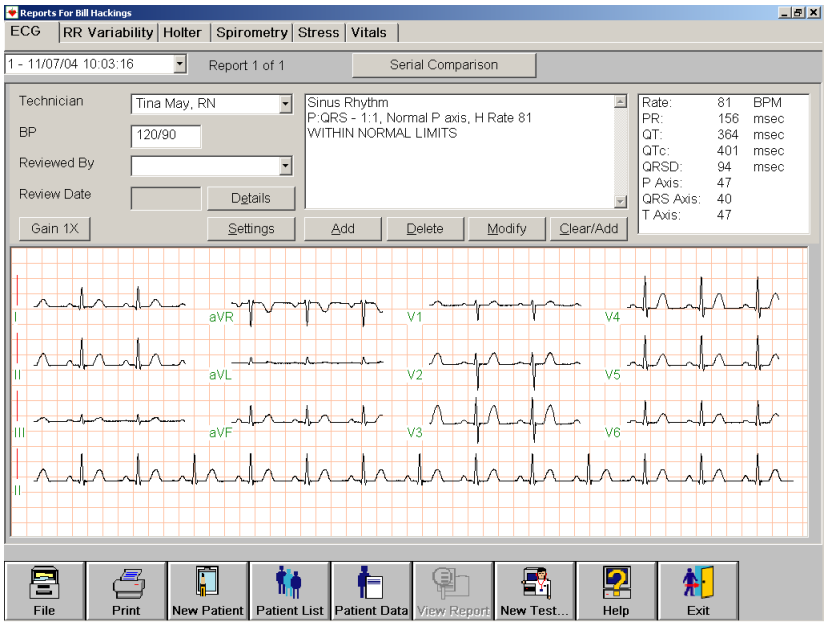


Figure 3.6 ECG Report Review Screen

The analysis results are displayed in the two text boxes on the upper right portion of the Report Review screen. The attending physician should review and evaluate the diagnostic interpretation and the measurements.

Editing Diagnostic Statements

Some patients have specific physiological profiles that can affect the IQmark Digital ECG interpretation of their results. If the physician believes there are any discrepancies in the diagnostic statements, the statements can and should be edited.

To delete or modify the diagnostic statement, simply select the statement you want to delete or modify, then click the appropriate button below the box. Click the Add or Clear/Add button to enter new diagnostic statements or to clear all statements and add new ones, as shown in the following screen.

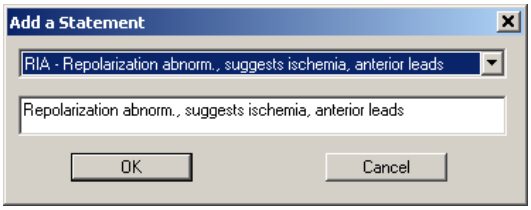


Figure 3.7 Add a Statement Screen

In the top box, type the abbreviation (e.g. RBBB) of a statement and the statement (e.g. Right bundle branch block) will appear in the edit box below. You can also select a statement from the list by clicking the down arrow. You can further edit the statement that appears in the lower edit box, or you can type in any statement you wish.

🔔 **NOTE:** If the statement list is empty, no default ECG statement list is selected in List Management. Refer to section II-E Configuring the IQmark Digital ECG on how to load the default statements through List Management.

If Disable Quick Edit is checked on the Default Interpretation and Acquisition Display Settings dialog box (see Table 2.0), the cursor is placed in the lower edit box by default for free text entry.

You can also edit the diagnostic statements through the Details screen (described later in this section).

The measurements displayed in the text box on the right (Fig. 3.6) can be changed if desired. Simply double-click the item you want to change, e.g. Rate, and a dialog box will appear allowing you to overwrite the current value.

🔔 **NOTE:** If Disable Interpretation is checked on the Default Interpretation and Acquisition Display Settings dialog box (Fig. 2.11), no interpretive statement appears in the ECG Report Review Screen, and the top center box is blank. The top right box, however, still displays the measurements.

If the ECG is a stat ECG, the word "STAT ECG" is displayed inside the ECG window above lead I.

ECG Report (Details) Review

Click the Details button to display a detailed measurement screen like the one shown below.

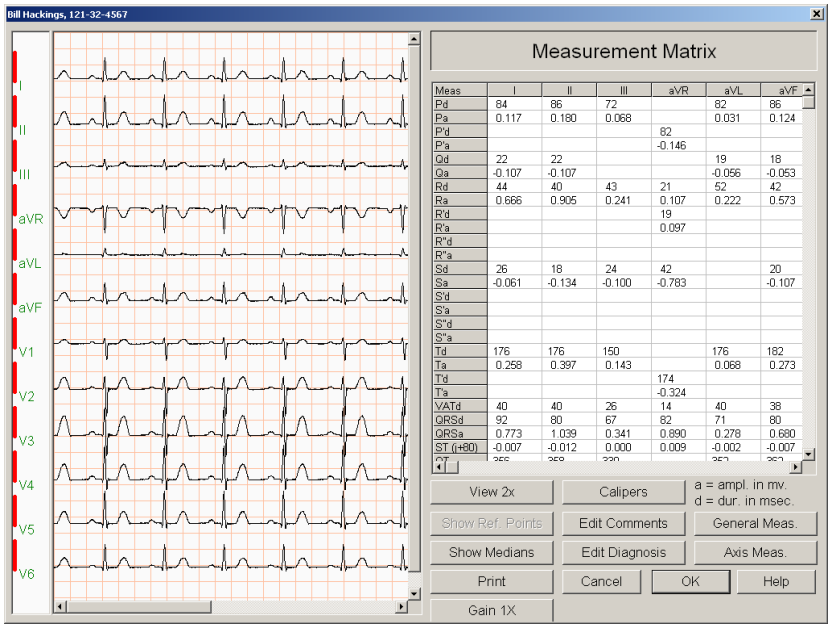


Figure 3.8 ECG Report Review (Details) Screen

Click the View 2x button in the ECG Report Review (Details) screen to magnify the 12-lead ECG tracings on the left to 2x zoom. Click the same button again and ECG tracings are displayed with 4x magnification.

The Show Medians button switches the ECG display between the median beats (representative beats) or the 10-second ECG tracings. While displaying the Show Medians beats, clicking the Show Ref. Points button displays the reference points for onsets and offsets of the P-QRS-T component waves of the median (representative) beats.

Click the Calipers button to select between "Simple Calipers" or "P-QRS-T Calipers." These electronic calipers allow you to measure the amplitude (mv) and duration (ms) of any part of the ECG waveform, making it easy to overread ECG tests online without printing them.

The Simple Calipers are shown on the following screen shot. To move the pair of Simple Calipers together with a fixed interval, place the mouse on one of the calipers, hold down the Ctrl (Control) key and drag to a desired location.

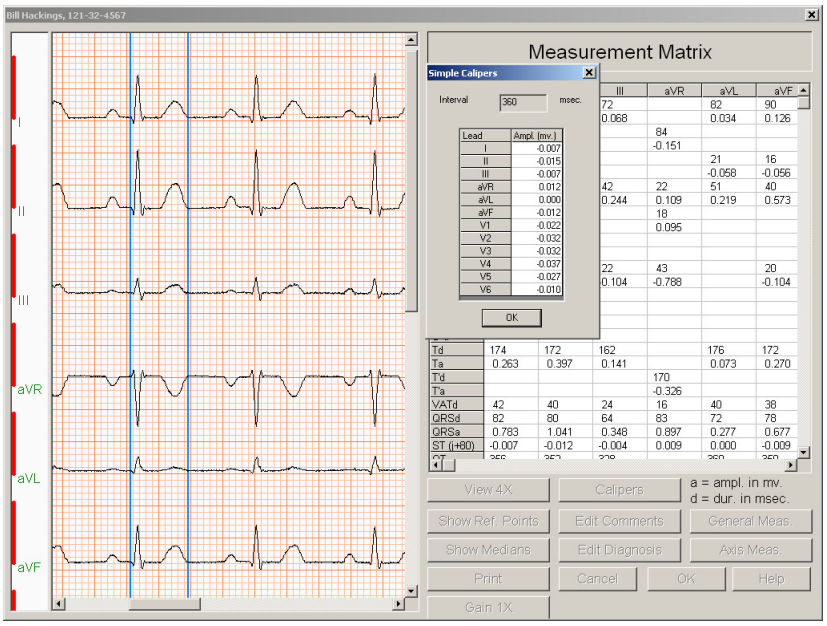


Figure 3.9 ECG Report Review (Details) Screen with Simple Calipers

The Edit Comments button displays a dialog box that allows entering and editing of the report comments. Report comments will be printed at the top of the ECG report. Edit Diagnosis displays a dialog box that allows editing of the diagnostic statements. See Fig. 3.10 below.

The General Meas. button displays a dialog box showing the general measurements, which are also displayed on the previous ECG Review screen (Fig. 3.6) and on the ECG report if printed. The Axis Meas. button displays a dialog box showing the axes (frontal, horizontal and sagital) for the P, QRS and T waves.

You can view and edit the diagnostic statements from this screen by clicking the Edit Diagnosis button. The Edit Diagnostic Statements dialog box appears.

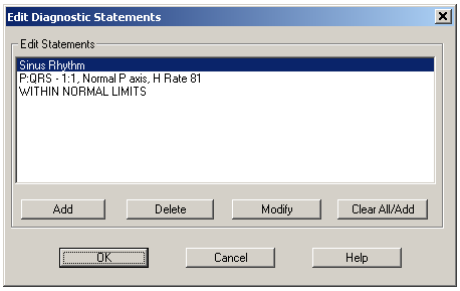


Figure 3.10 Edit Diagnostic Statements Screen

Refer to *Editing Diagnostic Statements* section above for details.

Serial Comparison

This feature enables you to compare up to four ECGs from the same patient. If the patient has more than one ECG report, click the Serial Comparison button on the Report Review screen (Fig. 3.6) and the Select ECG Reports dialog box appears. Choose the test selections you want and click OK.

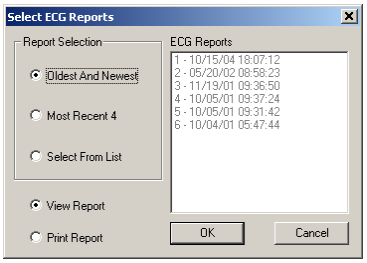


Figure 3.11 Select ECG Reports For Serial Comparison

The following sample Serial Comparison screen shows two ECG reports simultaneously. Summaries of each ECG report are displayed at the top right section. Each report is given a report number, shown to the left of the date. ECG tracings are color-coded to identify different reports, as indicated at the lower left corner. Clearing a report check box turns off the median beats for that report, displayed on the left side of the screen. Median beats are superimposed so that subtle differences can be viewed easily. Rhythm strips from each report are also displayed in the lower right section together with the report number and lead label. You can view different rhythm leads by clicking the down arrow button next to the Rhythm Lead indicator.

You can click inside the median beat or the rhythm strip area to zoom in on the ECG tracings. Click again and ECG views return to the previous scale.

Figure 3.12 Serial Comparison Screen

RR Variability Report Review

If a report was collected using the Start RR function, then the ECG data is displayed on the Report Review screen as shown below.

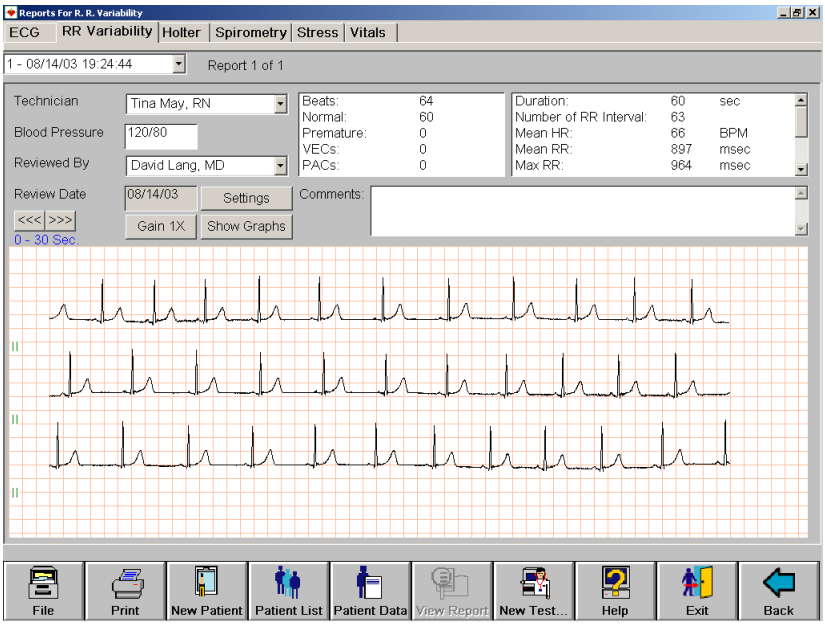


Figure 3.13 RR Variability Report Review (ECG) Screen

The diagnostic results for the RR Variability analysis are displayed in text boxes on the upper right portion of this screen. These results cannot be edited. You can view the patient's ECG tracing from the entire data collection period (30-360 seconds) by clicking the <<< | >>> arrows above the traces. Click the Gain 1X button if the amplitude of the ECG is too tall or too short. It will first increase the amplitude to 2X (20mm/mv). Click it again and it will decrease the amplitude to 1/2X (5mm/mv). Third click on the same button will return to the standard 1X gain (10mm/mv).

You can also review the data collected during the RR Variability analysis in R-R Trend and R-R Histogram formats by clicking the Show Graphs button. An example of this screen is shown.

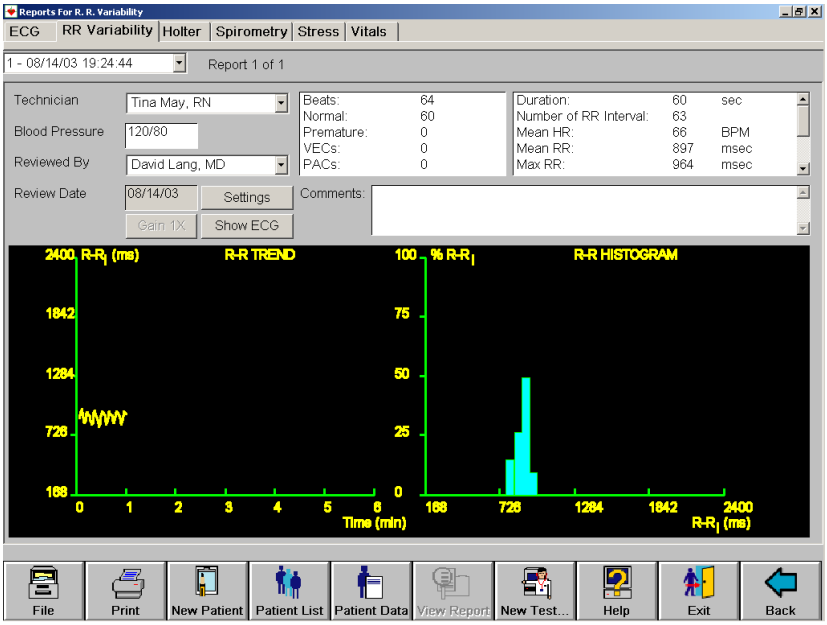


Figure 3.14 RR Variability Report Review (Graphs) Screen

On both the resting ECG and RR Variability Report Review screens, there are fields labeled Technician and Reviewed By. Ensure that the name of the technician doing the ECG is entered in the Technician field, and that the name of the doctor performing the ECG review and confirmation in entered in the Reviewed By field. These names are important as they serve to document the ECG collection process and will assist people reviewing these reports in the future.

Click the Print button to print the report displayed on the screen.

When you have finished reviewing the patient's reports, you can exit the Report Review screen by clicking the appropriate button on the bottom of the screen. If you edited the diagnostic statements, or filled in blank fields, you will be prompted to save your changes prior to exiting the screen. You are allowed to proceed to the appropriate screen regardless of whether you save your changes or not.

IV. Appendix

A. Operations at a Glance

A condensed guide to using the Midmark IQmark Digital ECG with new patients.

1) Start the IQmark Diagnostic Workstation program.

2) Select New Patient from the opening screen. For returning patient, select Patient List and search by patient's last name or ID.

3) Complete the fields on the Patient Data screen as accurately as possible. You must enter a name or ID number to perform a test. Enter the date of birth and sex of the patient. Enter the patient's vital signs. If the patient has a cardiac history, or is taking prescription medications, make sure you enter them on the appropriate tabs.

4) When the Patient Data screen is complete, prepare the patient for the resting ECG test. Refer to the enclosed Quick Reference User's Guide for a standard 12-lead hookup.

5) If the ECG module has an On/Off switch, you may need to turn it on by pressing the ⏻ symbol. The green LED on the module will light when the ECG module is on.

6) Select New Test on the menu bar, select the ECG test type and enter relevant information. Click OK when the patient is prepared and comfortable.

7) Adjust the sweep speed and gain as necessary. If artifacts or noise occur in the ECG signal, please refer to "ECG signal quality problems…" in the Troubleshooting Guide for corrective actions. Do NOT turn the MYO filter ON for pacemaker patients.

8) Wait for the ECG tracings to pass the screen twice (about 20 seconds) to verify that the signal quality is good and the baselines are stable.

9) To acquire a test report, click either the Analyze or the Start RR button on the menu bar.

   Analyze instructs the program to acquire, analyze and store a resting ECG test.

   Start RR instructs the program to acquire a preset duration of the rhythm strip and prepare a RR Variability report.

10) Reports are automatically saved and can be viewed upon exiting the ECG screen by the Review button.

11) Reports on the Report Review screen are in chronological order for the patient being tested, and are displayed on the ECG or RR Variability tabs.

12) You can review reports from other patients by clicking Patient List.

B. Troubleshooting Guide

This Troubleshooting Guide provides a comprehensive list of solutions and recommendations to problems you might encounter with the IQmark Digital ECG. Before calling Midmark Diagnostics Group for Technical Support, please refer to the following table for help. Error messages are displayed at the center or at the bottom right corner of the screen.

NOTE: For errors that occur during the analysis or management of ECG files, please refer to Troubleshooting Section in the *IQmark Diagnostic Workstation Operation Manual*.

Table 4.0 Troubleshooting Guide

Troubleshooting Guide	
Error Message or Problem	**Solution or Recommendation**
DATA FORMAT ERROR Message appears after starting a New ECG.	A format error has occurred in the ECG data collected. • This Error message can be cleared by clicking on Settings, then Cancel. • Verify that the Low Battery LED on the ECG Module is not blinking. If it is, install new batteries. • Switch to 4 leads display format. Refer to section on "Live ECG" for Display Setting change instructions. • Turn off the Waveform Smoothing option. Refer to section on "Live ECG" and Table 2.0, "Default Interpretation And Acquisition Display Settings." If an error message appears consistently at the beginning of New ECG, verify that the ECG module is connected to the correct serial port. Refer to sections II-B and II-.D.

Troubleshooting Guide

Error Message or Problem	Solution or Recommendation
Details button does not work in the ECG Report Review screen.	1. Exit the IQmark Digital ECG application. 2. Start MS-DOS Prompt. 3. Change directory to c:\windows\system (if Windows NT, c:\winnt\system32) 4. Type regsvr32 msflxgrd.ocx and press Enter 5. Type regsvr32 oleaut32.dll and press Enter 6. Exit MS-DOS Prompt and start the IQmark Digital ECG application.
DISPLAY DIAGNOSTICS: Delays in the ECG display have been detected. Click on Help to diagnose this problem. Message appears while running an ECG.	A. The graphics display adapter in the computer is too slow in displaying the live ECG for the current display settings. B. The computer might also be too slow or too busy running other programs in the background. C. If you are running live ECG in a thin-client environment, your bandwidth maybe too low. • Click on the Help button on the message window. Follow the recommendations on the help screen. • Verify that the Waveform Smoothing option is off and set to display in 4 leads display format. This is found under Default Interpretation and Acquisition Display Settings tab on Settings function (Fig. 3.5). • Verify that you do not have any other task or program running at the same time. Exit the IQmark Workstation and close all running programs. Start the IQmark Workstation program without restarting the computer. • If the above fails to correct the problem, disable the Display Real-time ECG Tracing under Default Interpretation and Acquisition Display Settings tab on Settings function (Fig. 3.5).

Troubleshooting Guide

Error Message or Problem	Solution or Recommendation
ECG MODULE NOT RESPONDING! Message appears after starting a new ECG test. No ECG tracing is displayed on the screen.	The program cannot communicate with the IQmark Digital ECG module because it is not on, not connected to the computer, or connected to the wrong port. **Note** for **Palm Pilot** or other similar PDA users: If you are using the same COM or USB port for the IQmark Digital ECG and Palm Pilot, exit the Hot Sync Manager (or similar software) before running the IQmark Digital ECG application. **Note** for **Touchscreen Display** users: If you are using the same COM or USB port for IQmark Digital ECG and the Touchscreen Display, close or disable the touchscreen driver before running the IQmark Digital ECG application. • Verify that the ECG module is connected to the correct serial port. Refer to sections II-B and II-D. • For Valentine ECG module: Verify that the ON LED on the ECG Module is lit. If it is not, push the POWER button on the ECG Module to turn on its power. • For Valentine ECG, verify that the Low Battery LED is not blinking. If it is, install new batteries. • For IQmark Digital ECG module: Verify that the LED on the top cover is green. If the LED is red, install new batteries. If there is a ⏻ symbol on the module, you may need to press it to turn on its power.
ECG signal quality problems such as a low amplitude, wandering baseline, noisy signal, etc.	In order to have good ECG signal quality, it is essential that the patient is properly prepared, the lead placements are correct, the electrodes and lead wires are secured firmly. Follow Section III-B, "Preparation" closely for best performance. • For the Valentine ECG: Verify that the Low Battery LED on the ECG Module is not blinking. If it is, install new batteries. For the IQmark Digital ECG module: Verify that the LED is not red or the "Low Battery" message is not displayed on the screen. If it is, install new batteries. • Verify that the electrodes are fresh, moist, and sticky, not dry or hard. Check electrode expiration date on package. • Verify that the patient lead wires and cables are not damaged or worn out.

Troubleshooting Guide	
Error Message or Problem	**Solution or Recommendation**
	• Inspect connections between the electrodes, clips, lead wires, lead cable and the ECG Module. • The exam room should not be too cold. Patient under test may shiver, causing a noisy signal. • If any of the I, II, III, aVR, aVL and aVF leads on the screen are noisy or flat-lined, always check the *limb lead* electrodes for proper contact in this order: RL, LL, RA and LA. If a precordial lead is noisy or flat-lined, check the limb lead electrodes first, and then check the corresponding chest lead electrode for proper contact. Once identified, discard and replace the used electrode. Prepare the problem site again or try a new electrode site in close proximity to the original site. Note any site variance on test report. • If after the above steps, noise or artifact still occurs in the ECG, then try the filter settings on the ECG screen. Turn AC filter ON if you see 50/60Hz noise. Turn MYO filter ON if patient produces muscle tremor. Turn Drift filter ON if the ECG baseline is drifting. While these digital filters can improve signal quality, they cannot correct hookup problems. **Note**: As with any ECG measuring device, turning on the MYO filter may alter measurements, which in turn may affect the diagnostic statements. Do NOT turn on the MYO filter for pacemaker patients. • Click the INST button to help reset the baselines, or manually turn off and on the ECG module. • Verify patient's bed is properly grounded. • Verify patient or examination room is not susceptible to energy interference such as electromagnetic fields from high power equipment like X-ray machines, power generators, power compressors, etc.

Troubleshooting Guide	
Error Message or Problem	**Solution or Recommendation**
ECG SECURITY KEY NOT FOUND Message appears after clicking the Analyze button. This message only appears when using the Valentine PC-ECG module and not with the IQmark Digital ECG module.	The Workstation cannot find the Security Key for the Valentine PC-ECG because it is either not installed or there is a conflict with the parallel port. • Verify that the Security Key is installed directly on the parallel (printer) port of the computer and that the printer cable is connected to the back of the Security Key. Ensure that the printer is ON and READY (or ON-LINE). • Print from Windows Notepad or any text file to verify the parallel port is working properly with the Security Key installed.
ERROR: THERE MUST BE AT LEAST 2 REPORTS FOR SERIAL COMPARISON /TRENDING. Message appears after clicking the Serial Comparison button.	Serial comparison in ECG requires at least 2 ECG reports completed under the same patient. • Click OK. Perform additional test if needed.
Incorrect diagnostic interpretation.	• Refer to solution for "ECG signal quality problems" in this section. • Patient's Date of Birth, Sex and Medications must be accurately entered. Refer to section III-E, "Testing A New Patient." • Edit the diagnostic statements accordingly. Refer to "ECG Report Review" in section III-F.
No error message and no ECG trace on Live ECG screen.	• Refer to solutions for ECG MODULE NOT RESPONDING! in this section. • Refer to solution for SERIAL PORT ERROR! in this section.

Troubleshooting Guide

Error Message or Problem	Solution or Recommendation
Prints too slowly when printing live ECG tracing or printing automatically after analysis.	Depending on your computer, print jobs may be slower if the IQmark Digital ECG is still actively collecting live ECG data. • Click Freeze before printing the ECG tracing displayed on the screen. Refer to "Live ECG" in section III-E. • Verify that Print After Analysis is not checked. Refer to Settings section, table 2.1 ("Printer Format Settings") and table 2.2 ("RR Variability Settings"). • Uncheck Grid setting (Refer to Table 2.1 "Printer Format Settings.") Printing ECG reports without the grid will expedite the print jobs.
SERIAL PORT ERROR! EXIT. Message appears after starting a New ECG. No ECG trace is displayed on the screen.	The IQmark Digital ECG cannot communicate with the ECG Acquisition Module. It is either connected to the wrong serial port or the setup in the IQmark Configuration is incorrect. **Note** for **Palm Pilot** or other similar PDA users: If you are using the same COM port for IQmark Digital ECG and the Palm Pilot, exit the Hot Sync Manager (or similar software) before you run the IQmark Digital ECG application. **Note** for **Touchscreen Display** users: If you are using the same COM port for the IQmark Digital ECG and the Touchscreen Display, close or disable the touchscreen driver before running the IQmark Digital ECG application. • Refer to sections II-B and II-D for communication port selection and setup. Use the Auto Detect feature to find the correct COM port.
All other operational problems.	• Please refer to the online help by clicking on the Help button found on all screens. • Additional troubleshooting covering ECG diagnostics is available in the IQmark Diagnostic Workstation Operation Manual, available through Midmark Customer Service. • For technical support, please see the contact information at the end of this manual.

C. Maintenance and Storage

Cleaning

CAUTION

Do not use aromatic hydrocarbons, rubbing alcohol, or chlorinated solvents for cleaning the ECG module. Do not use alcohol or acetone on lead wires or cables since they can stiffen and crack the insulating plastic.

Clean the outside of the ECG module with a mild solution of detergent and water using a soft cloth. Avoid using excessive amounts of solution, which may infiltrate the connectors, battery compartments or ECG Module. If necessary, use a mild sterilizing detergent with low alcohol content generally used in hospitals. **Verify that all equipment, including accessories, are completely dry before using.**

Preventative Inspection

A preventative inspection should be done prior to each use of the ECG module. This is done to verify that there is no visible damage to the unit that may cause it to malfunction.

Visual inspection should include the module and all cables for signs of damage and deterioration, including but not limited to cracks, cuts, discoloration or oxidation. If a cable or other accessory exhibits any of these symptoms, replace it immediately prior to using the ECG module.

Storage

To prevent damage to the IQmark Digital ECG module due to battery leakage or oxidation, remove all batteries if the IQmark Digital ECG module is not to be used for a long period of time. Avoid extreme humidity and heat during storage.

Radio and Television Interference

This equipment generates and uses radio-frequency energy. If not installed and used properly in strict accordance with the manufacturer's instructions, it may cause interference to radio and television reception.

This equipment has been tested and proved to be in compliance with the standards for medical devices and in accordance with the IEC 601-1 rules, which are designed to provide reasonable protection against such interference in a medical or hospital environment.

D. Customer Support

For immediate help diagnosing any problems with this product, refer to the online help or the Troubleshooting Guide. Otherwise, contact Midmark Technical Support at (310) 530-5955. Inside the Continental United States dial (800) 624-8950. Office hours are 8:00 AM- 5:00 PM, Pacific Standard Time.

Warranty

All Midmark Diagnostics Group's products are warranted to be free from manufacturing and material defects for 12 months from the date of purchase. Any misuse or abuse of a Midmark product voids all applicable warranties.

Return Materials Authorization

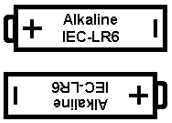
To return any product for repair, an RMA (Return Materials Authorization) number must be obtained from a Midmark Customer Support representative. Mark this number on all the packaging containing the items to be returned and in any correspondence regarding the return.

Shipping

Before shipping any unit to Midmark, be certain that an RMA (Return Materials Authorization) number has been issued and that all guidelines regarding this authorization are followed. We highly recommend that you follow all guidelines for the shipment of medical products set forth by the shipping company you choose to use. If a question should arise regarding the appropriate method of shipment, please feel free to ask when calling for your RMA number. It is ultimately the responsibility of the customer when shipping a product to ensure that all packages and their contents get to Midmark safely. **Midmark will not assume responsibility for damage incurred by improper packaging, shipment, or product use. Such actions will void all applicable warranties.**

F. Safety and International Symbols

The following symbols are used on Midmark products. These symbols appear on products when applicable. Refer to this directory for details concerning the symbols used on equipment.

Symbol	Description
	ATTENTION Refer to manual for instructions
	Year manufactured
	Battery Orientation This device uses 2 AA Alkaline batteries. The icon indicates the orientation of batteries to be installed.
	DC Voltage This device uses 3 Volt power and consumes 30mA when in use.
	CE Mark. Equipment displaying this symbol has passed specific safety tests and adheres to international quality standards established by the European Community.
	IEC-601 Defibrillator-proof Type CF equipment. Equipment displaying this symbol contains an F-type isolated (floating) applied part that provides a high degree of protection against electrical shock, and is suitable for use during defibrillation.
	ETL Listing Mark. Equipment displaying this symbol has been tested and complies with the following safety standards: Conforms to UL STD 2601-1 Certified to CAN/CSA STD C22.2 No. 601.1

G. Glossary

ARCHIVING	Placing data into temporary storage where it cannot be damaged or altered. Archived data, such as ECG reports prepared by the IQmark Workstation, can be retrieved at a later date for review.
IQMARK DIAGNOSTIC WORKSTATION	The name of the software application you install on your Microsoft Windows based computer, in order to use the Midmark IQmark Digital ECG.
CLICK	In this manual, Click refers to tapping a mouse button once – quickly and firmly. For example, if you want to pull down the Medications menu, you will Click on the menu name. Double Click refers to performing this task twice, and is generally used to start programs.
DATABASE	A collection of data arranged into methodically organized categories. In this manual, the term refers to the collection of ECG reports that the IQmark Digital ECG stores on your hard drive.
DESKTOP	The background image that appears on your computer screen behind the application window(s).
DIALOG BOX	An on-screen form you complete to provide the IQmark Workstation with information needed to accomplish tasks; an example is the Medications window.
ECG	See electrocardiogram.
Email	Electronic mail that is sent from one computer to another via telephone lines through Internet access. Patient reports are sent as attachments to the email.
ELECTROCARDIOGRAM	A graphic recording that displays the electrical activities of the heart. Permits the detection of abnormalities in the transmission of the cardiac impulse through the heart muscle and serves as an important aid in the diagnosis of heart ailments. During an electrocardiogram, the heart's electrical impulses are typically measured through electrodes placed on the chest and limbs.
ELECTRODES	A device used as an interface between an electrical conductor and an organism.
FOLDER	Folders, which function like the drawers in a filing cabinet, are used by Windows to organize files and applications. The IQmark Workstation application resides in a folder named "Brentwood," located on your hard drive.
MICROSOFT WINDOWS BASED COMPUTER	Any computer that runs on Microsoft Windows operating system. The Midmark IQmark Digital ECG requires a personal computer that runs on Windows 2000 or XP platform, for operation.
MY COMPUTER	A Microsoft Windows icon that appears on the desktop in the form of a stylized computer. Clicking on My Computer allows you to explore your computer's disks, printers, Control Panels and other functions.
IQmark DIGITAL ECG	Midmark Diagnostics Group's portable ECG device for converting a Microsoft Windows based PC into an electrocardiograph with interpretive capability. The IQmark Digital ECG is operated using the IQmark Diagnostic Workstation software application.
PORT	A place where data is passed in and out of a computer. Windows

	based PCs typically have several ports on the computer. The IQmark Digital ECG communicates the data it collects from patients through a serial or USB port.
SERIAL PORT	A 9- and/or 25- pin port that is used by computers to communicate serial data. These ports are typically labeled COM1 and COM2. Hardware that typically uses these ports includes the mouse, modem, printer, etc. The IQmark Digital ECG connects to a 9-pin serial port, or a 25-pin serial port if an adapter is used. Consult your computer owner's manual for more information on configuration and capabilities.
SHORTCUT ICON	Generally appearing on the desktop, shortcut icons allow you to open a document, application, or folder simply by double clicking on them.
START BUTTON	Appears at the left end of the Microsoft Windows Taskbar, and allows you to start applications, open files, get to the Control Panel and exit Windows. This feature first appeared with Windows 95. Consult your Windows owners' manual for more information.
TASKBAR	By default, it appears as a horizontal bar at the bottom of your screen. The Taskbar provides rapid access to the Start Button and applications you have started. Set the Taskbar to Autohide will provide the IQmark Workstation with maximum display area. Refer to section II-C *Software Installation* or see your Windows owner's manual for more details.
USB PORT	Universal Serial Bus is a high-speed communication port with plug-and-play support. Windows 95 and NT do not support USB port.
TEXT BOX	A box where one is able to type in text relative to an application or task. Select the text box by clicking on it, then start typing.

V. IQmark Digital ECG Service Manual

1.0 INTRODUCTION

The Midmark IQmark Digital ECG is a PC-based diagnostic instrument that converts any Windows-based personal computer to a 12-lead electrocardiograph with interpretative and data storage capabilities. A complete IQmark Digital ECG system consists of the ECG data acquisition module, the PC system, which includes the monitor and the printer, the Microsoft Windows operating systems (Windows 98, Windows NT 4.0, Windows 2000 and Windows XP), and the IQmark Diagnostic Workstation software program.

This manual is provided to assistance primarily with service of the IQmark Digital ECG data acquisition module. For information regarding the service and operation of the PC system, please consult the IQmark Digital ECG operation manual or the documents provided by PC manufacturers.

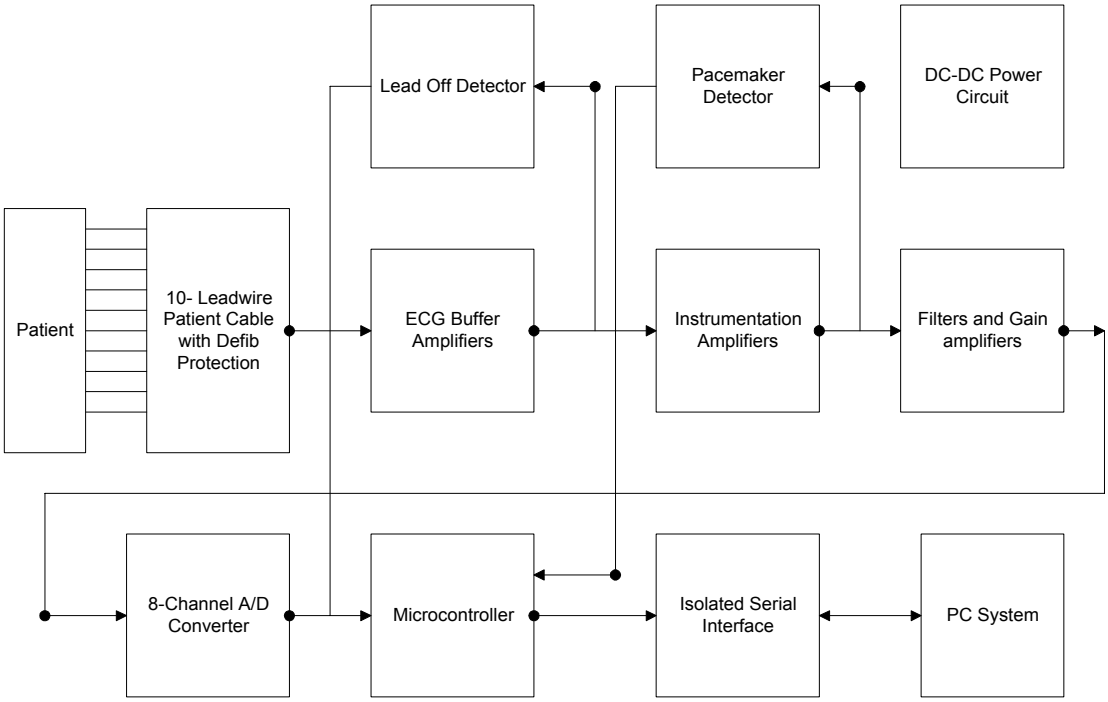
2.0 THEORY OF OPERATION

The IQmark Digital ECG data acquisition module is an improved version of previous hardware modules.

Some new features for the IQmark Digital ECG data acquisition module include:

- Built-in defibrillation protection circuit
- Hardware lead-off detection circuit
- Hardware pacemaker detection circuit
- Analog bandwidth from 0.05Hz to 150 Hz
- Digital sample rate of 500 Hz.
- USB computer interface (Model Specific)
- RS-232/COM port interface (Model Specific)
- Pocket PC compatible interface (Model Specific)

2.1 SYSTEM BLOCK DIAGRAM



2.2 10-Leadwire Patient Cable

The IQmark Digital ECG uses the special Midmark 10-Leadwire patient cable for its 12-lead ECG data acquisition. The patient cable has 10 conductor shielded lead wires. There is a 1Kohm (±10%) resistor embedded inside each lead wire. Together with the voltage clamping circuit built into the ECG front end, the IQmark Digital ECG provides the built-in defibrillation protection capability required by AAMI EC-11 and IEC-60601.

2.3 ECG Buffer Amplifiers

The patient ECG signals are first fed to the 8 ECG buffer amplifiers. These buffer amplifiers provide high input resistance for the patient interface with low output resistance to the instrumentation amplifiers.

2.4 Instrumentation Amplifiers

There are eight differential instrumentation amplifiers used in the IQmark Digital ECG, providing eight output signals from CH0 to CH7. Each differential amplifier has two inputs, positive and negative.

The following table lists the positive and negative inputs for each channel.

Channel Number	Positive Input	Negative Input
CH0	LA	RA
CH1	LL	RA
CH2	V6	Wilson Center
CH3	V5	Wilson Center
CH4	V4	Wilson Center
CH5	V3	Wilson Center
CH6	V2	Wilson Center
CH7	V1	Wilson Center

The Wilson Center is a reference point combined with the three limb leads. The purpose of the instrumentation amplifier is to provide a high CMRR (Common Mode Rejection Ration), rejecting common mode signals such as 60 Hz line noise.

2.5 Filters and Gain Amplifiers

After the instrumentation amplifiers, the 8-channel ECG signals are passed into two stages of filters. The first stage consists of eight first-order high-pass filters with a cutoff frequency of 0.048Hz. The second stage consists of eight low pass filters with a cutoff frequency of 159Hz. The ECG signals are also amplified to match the AD converter input dynamic range of 0-2.5V.

There are eight test points provided on the PCB board. The test points are labeled as CH0, CH1, CH2, CH3, CH4, CH5, CH6 and CH7. The signals measured on these test points are amplified with a gain of 125 and DC offset to 1.25Volt.

2.6 Analog to Digital Conversion

The AD converter used is ADC12138 from National Semiconductor. The AD converter is 12-bit plus sign serial I/O A/D converter with MUX and Sample/Hold. The amplified and filtered 8-channel ECG signals are passed to the 8-channel inputs of the AD converter. The sampling rate for each channel is 500 Hz. The digitized ECG data are sent to the microcontroller through the serial interface.

2.7 Microcontroller

The microcontroller is a PIC16LC67 chip from Microchip Technology. This chip has 8Kx14 OTP, 33 I/O lines and built-in serial interfaces for A/D converter and RS232. The microcontroller receives the digitized ECG data from the AD converter and encodes the data with packets and sends out to the PC through serial

interface circuitry. The setting for the RS232 is 8 bit data, 1 bit stop, no parity, and 115,000-baud rate and is usually handled automatically. Settings for USB are automatic and are not user selectable.

2.8 Isolated Serial Interfaces

To provide the maximum safety for the patient, the IQmark Digital ECG hardware and the PC are isolated with an optical coupler and or isolated DC to DC converters. The serial signal sent out by the PIC microcontroller is coupled optically to the PC system either through the RS232 or USB interface. There is no electrical connection between the patient and the PC system. The isolation circuit can withstand up to 1000 volts.

2.9 Lead off Detector

The IQmark Digital ECG has a built in lead off detection circuit. The lead off circuit senses the lead off condition and reports to the PIC microcontroller. The PIC microcontroller sends out the lead off condition to the PC through the serial interface.

2.10 Pacemaker Detector

The pacemaker detection circuit in the IQmark Digital ECG ensures the device's capability of printing the ECG signal in the presence of pacemaker pulses with amplitudes between 2 and 250 mV, duration between 0.1 and 2.0 ms recommended by AAMI EC-11.

2.11 DC-DC Power Converter

The IQmark Digital ECG (42 Series / RS232) uses two AA batteries to supply its power.
The IQmark Digital ECG (43 Series / USB) does not require the use of batteries. The USB port of the host computer provides the operating power. A step up DC-DC converter is used to provide a 4.5 Volt power source. Two 3.3 Volt regulators are used to provide two 3.3 Volts power source for the analog circuits and digital circuit for the unit. There is also a negative voltage converter used to generate a 3.3 Volt power source for the analog circuit. A Linear Technology 1.25 Volt micropower shunt reference regulator provides precision 1.25 Volt reference voltage.

The IQmark Digital ECG (42 Series / RS232) power is switched ON or OFF via the switch marked I/O on the top label. The IQmark Digital ECG (43 Series / USB) power is switched ON or OFF by the ECG program through the USB port. Isolation is provided for signals entering the ECG module and can withstand up to 1000 volts.

3.0 SYSTEM MAINTENANCE AND OBTAINING SERVICE

The IQmark Digital ECG is a portable device, which requires little maintenance. To ensure the best performance of the device, the following procedures are recommended:

(1). Keep the patient cable clean.

(2). Do not unplug the patient cable from the IQmark Digital ECG hardware.

(3). When the device LED turns red or the computer screen displays low battery, (42 Series / RS232 version only) replace the batteries inside the unit before continuing.

The IQmark Digital ECG acquisition module contains no user adjustable or serviceable parts. For repair or technical support, refer to the information below.

NOTE: Return authorization is required prior to the return of the device. Midmark Diagnostics Group personnel will issue a RETURN MATERIALS AUTHORIZATION (RMA) number prior to shipment.

Midmark Diagnostics Group
Customer Service/Technical Support
Tel: (310) 530-5955 ext. 2
Fax:(310) 530-1421

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